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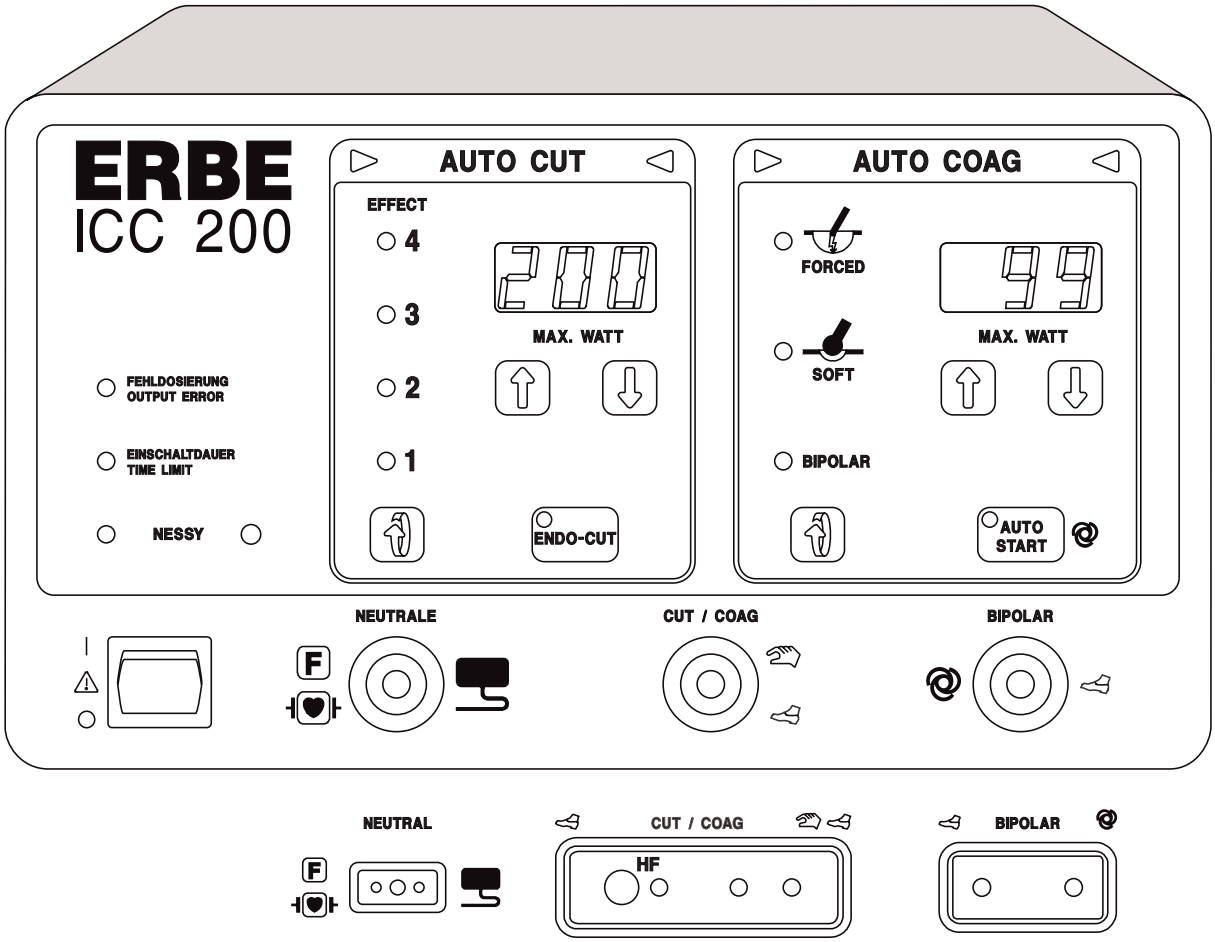

ERBOTOM ICC 200

Instruction manual

04.05

ERBOTOM ICC 200 V 2.X

10128-002, 10128-009, 10128-303, 10128-027, 10128-403

ERBOTOM ICC 200 E V 2.X

10128-010, 10128-015, 10128-304,10128-028

ERBOTOM ICC 200 EA V 2.X

10128-023, 10128-036, 10128-305, 10128-058, 10128-400

Instruction manual
04.05

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ADDRESSES

1 INTRODUCTION

1.1 Intended purpose of the ICC 200

The ICC 200 is a high-frequency surgical unit for cutting and coagulation. The ICC 200 is available in the variations Basic Model, Basic Model with ENDO CUT (ICC 200 E), Basic Model with ENDO CUT and Argon Plasma Coagulation (ICC 200 EA).

1.2 Explanation of the safety instructions

The WARNING! safety instruction indicates a danger which can result in personal injury.

The CAUTION! safety instruction indicates a danger which can result in property damage.

The IMPORTANT safety instruction indicates a danger which can cause functional failure of the unit.

2 INITIAL OPERATION

Read carefully before initial operation of the unit.

In the development and production of this high-frequency surgical unit, the relevant, generally recognized rules of technology, as well as the valid occupational safety and accident prevention regulations have been taken into consideration. This ensures that patients, employees and third parties are protected from dangers to life and health during intended application of the high-frequency surgical unit, to the extent permitted by the type of application intended.

Initial operation

Before delivery, every high-frequency surgical unit is tested by the manufacturer in regard to its function and safety. To ensure that the unit also functions safely after shipping and installation at the operator's site, the following points should be observed:

The operator should only operate the high-frequency surgical unit if the manufacturer or supplier

1. has subjected the unit to a performance test on site

2. has instructed the parties responsible for operation of the unit in handling of the unit by means of the instruction manual.

3 RISKS AND SAFETY OF HIGH-FREQUENCY SURGERY

3.1 Unintentional thermal tissue damage

High-frequency surgery is associated in principle with various risks for the patient, the personnel and surroundings. In order to avoid these risks in practice, the surgeon and his/her assistants must recognize these risks and observe the appropriate rules for prevention of damage. In the following, these risks and rules for prevention of damage are explained.

3.1.1 Unintentional thermal tissue damage due to HF leakage currents

During high-frequency surgery, the patient unavoidably conducts high-frequency electrical current to ground potential. If the patient makes contact with electrically conductive objects during high-frequency surgery, a high-frequency electrical current can result at the contact point between the patient and this object, which can in turn cause thermal necroses. Not just objects made of metal are electrically conductive objects, but also wet cloths.

WARNING!

The patient must be insulated against electrically conductive objects during high-frequency surgery. The black elastic table covers on operating tables demonstrate a certain electrical conductivity for diverting electrical charges. Therefore they are never suitable for ensuring the required insulation of the patient against metal parts of the operating table. For this reason, an electrically insulating intermediate layer, for example dry cover cloths, must be laid between the patient and this black operating table cover during the application of high-frequency surgery.

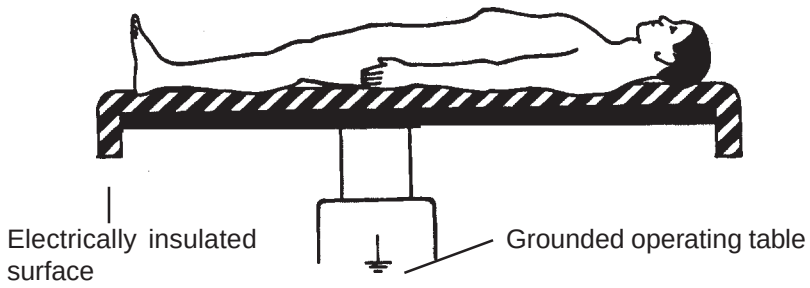


Fig.: Insulated positioning of the patient on the operating table

If it is possible for this intermediate layer to become wet during the operation, for example due to perspiration, irrigation liquid, urine etc., wetting of these intermediate layers must be prevented by a watertight sheet of plastic. Urine should be carried away via catheter.

- Extremities lying against the trunk or skin-to-skin contact points should be insulated from one another by laying dry cover cloths between them.
- Do not apply ECG electrodes closer than 15 cm next to the operating field.
- Needle electrodes or injection cannulae should not be used as ECG electrodes during high-frequency surgery.

3.1.2 Unintentional activation of an HF generator

Unintentional activation of an HF generator can lead to burns on the patient if the active electrode hereby touches the patient directly or indirectly through electrically conductive objects or wet cloths.

Unintentional activation of an HF generator can, for example, be caused by:

- Unintentionally pressing a footswitch pedal
- Unintentionally pressing a fingerswitch
- Defective fingerswitches, footswitches or cables
- Penetration of electrically conductive liquids (blood, amniotic fluid, urine, physiological saline solution, irrigation fluids etc.) into fingerswitches or footswitches.
- Errors within the high-frequency surgical unit

WARNING !

To prevent burns on the patient due to unintentional activation of a high-frequency generator, the following application rules should be heeded:

- Never lay active electrodes onto or beside a patient in such a way that they can touch the patient directly or indirectly through electrically conductive objects or wet cloths.
- The lines to the active electrodes should be positioned in such a way that they touch neither the patient nor other lines.
- Always set the acoustic signal, which indicates the active status of the high-frequency generator, so that it can be easily heard.
- For operations in which the cutting or coagulation electrode unavoidably remains in contact with the patient even in a nonactive condition, e.g. for endoscopic operations, particular care is required. If such an electrode is unintentionally activated due to an error, this activated electrode should then not be removed from the body without special supervision. When removing the activated electrode from the patient's body, burns can result on all areas within the body which come into contact with the activated electrode. For this reason, in case such errors occur, the power switch for the high-frequency surgical unit should be switched off immediately before an attempt is made to remove the activated electrode from the body.

3.1.3 Unintentional thermal tissue damage due to inappropriate application

Generally speaking, the bipolar coagulation technique should be applied in preference to the monopolar coagulation technique. This particularly applies to coagulations on straight organs, on which the high-frequency current flows over longer areas through diameters which are approximately equal or become even smaller.

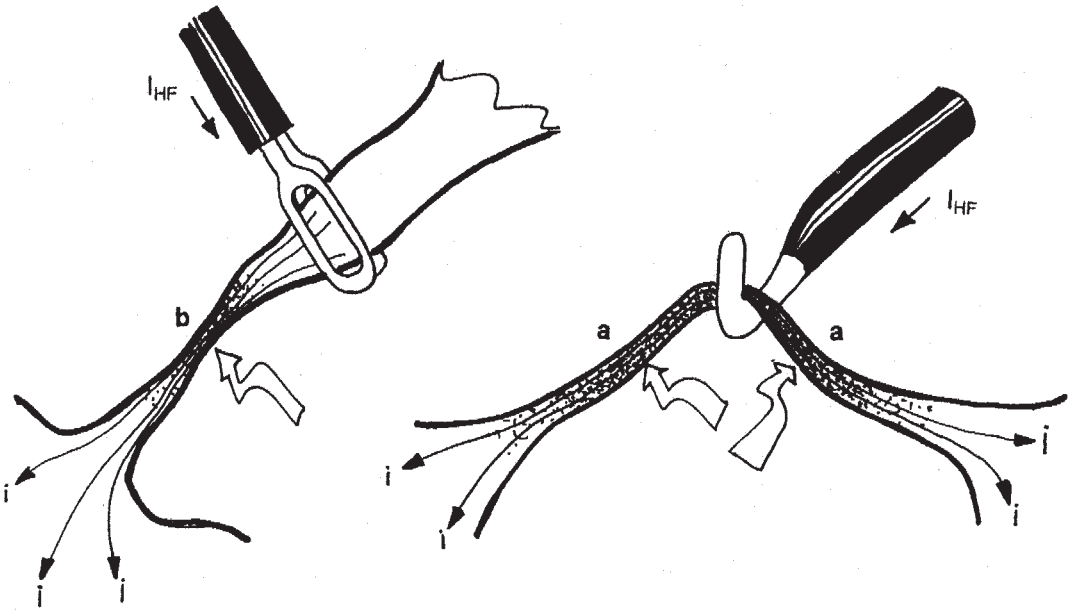


Fig.: Thermal damage of lateral tissue
The tissue is always first heated at places on the tissue where the diameter is smallest. If the HF current flows through the same diameter (a) over longer distances, the tissue coagulates over this entire distance. If the diameter of the tissue next to the application point of the coagulation electrode is smaller than at the point of application, coagulation will also occur next to the application point (b).

WARNING!

Always make certain that the HF current does not flow through thin tissue structures or vessels with a small diameter.

3.1.4 Unintentional thermal tissue damage due to inappropriate or nonapplication of the neutral electrode

With inappropriate or even nonapplication of the neutral electrode, there is a large risk of unintentional thermal tissue damage both at the application point of the neutral electrode as well as to other areas on the patient's body.

The neutral electrode must be applied with its entire surface as closely and reliably as possible to the operating field on the patient's body.

WARNING!

The effective contact surface, i.e. the electrical conductive value between the neutral electrode and the patient must correspond to the HF capacity used, meaning the intensity of the HF current. Here the effective contact surface means the surface of the neutral electrode which has electrically conductive contact to the skin of the patient during high-frequency surgery.

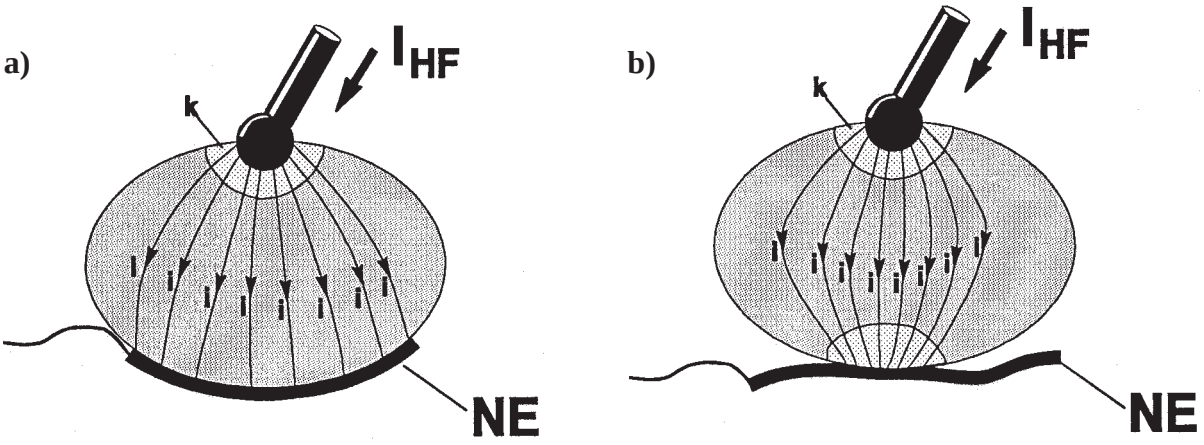


Fig.: The neutral electrode must be applied at an appropriate location on the patient's skin using the entire contact surface available (a). If the neutral electrode has only partial contact to the patient's skin (b), there is a risk that burning will occur at this location

3.1.5 Unintentional thermal tissue damage due to unsuitable and/or faulty accessories

It must be ensured that only accessories in perfect condition are used for high-frequency surgery. Only accessories that are compatible or tested by the unit manufacturer must be used. This applies both to the active electrodes including cable and plugs, as well as to the neutral electrodes including cables and plugs.

When using an instrument with electric insulation, it is necessary to be certain that these insulations are not overloaded and destroyed by overly high electric voltages. The electric output voltages for the high-frequency surgical unit are indicated for the various cutting and coagulation modes relative to the possible settings in this instruction manual. The electric strength of the instrument insulation can be found in the technical data for the instruments or, in case of doubt, can be requested from the manufacturer of the respective instrument.

WARNING!

All insulation on electrodes, electrode holders, cables, plugs etc. must be in perfect condition.

3.1.6 Unintentional thermal tissue damage due to inattentiveness

Like a scalpel, high-frequency surgery is always a potential source of danger if handled without care.

WARNING!

The cutting or coagulation electrodes should always be handled with care and laid aside in the intervals between use so that neither the patient nor other persons can come in contact with the electrodes.

Laying unused electrode handles or coagulation forceps on the patient, next to the patient or within folds on the cover cloths is dangerous. Cases of burns on patients are known which were caused by laying the coagulation forceps within folds on the cover cloths which penetrated through the cloths into the patient's skin and resulted in burns without being noticed.

3.1.7 Unintentional thermal tissue damage due to output error

The risk of unintentional thermal tissue damage is proportionate to the intensity and time limit set on the unit for cutting or coagulation.

WARNING!

The intensity for cutting or coagulation should only be set and only activated for as long as necessary for the intended purpose.

An insufficient effect at a standard setting can, for example, be caused by poor attachment of the neutral electrode, poor contact in the connectors, defective cables or electrically insulating tissue remnants on the active electrode. This must be checked before setting at a higher power.

3.1.8 Unintentional thermal tissue damage due to the ignition of flammable liquids, gases and/or vapors

During high-frequency surgery, electric sparks or arcs that can ignite flammable liquids, gases or vapors occur at the active electrode.

WARNING!

Make certain during high-frequency surgical operations that anesthetics, skin cleaning agents and disinfectants are nonflammable. If their use is unavoidable, they must have completely evaporated and the vapor must be removed from the area of spark formation before switching on the high-frequency surgical unit.

Before application of high-frequency surgery in the gastro-intestinal tract, it must be ensured that no flammable (endogenous) gases are present here. There is danger of explosion if flammable gases are present. For this reason, these gases must be extracted and/or eliminated by flushing out the affected lumen with CO_2before using high-frequency surgery.

During transurethral resection (TUR), H_2O molecules may dissociate into H_2 and O_2 in the arc between the resection loop and the irrigation liquid. These gases may collect on the roof of the urinary bladder as a highly explosive gas mixture. If resection is performed in this gas mixture, dangerous explosions may occur.

3.1.9 Unintentional burns due to hot electrodes

Cutting and/or coagulation electrodes become hot during cutting and/or coagulation procedures indirectly through the heated tissue and through the electric arc.

WARNING!

Tissue can be unintentionally burnt immediately after cutting and/or coagulation procedures if electrodes that are still hot touch the tissue. Attention must be especially paid to this during endoscopic operations, such as during pelviscopic fallopian tube coagulation or during endoscopic polypectomy.

3.2 Electric shock

An electric shock may occur if the high-frequency surgical unit delivers a too heavy low-frequency current or if a too heavy low-frequency current flows through the patient into the high-frequency surgical unit from another voltage source.

3.3 Stimulation of nerves and muscles

A known risk of high-frequency surgery is the unintentional electric stimulation of the patient's nerves and muscles. This stimulation can result from low-frequency electrical currents that are caused either by low-frequency current sources or due to electrical arcs between an active electrode and the patient's tissue.

Electric alternating current with a frequency above 300 kHz is unable to stimulate nerves and muscles.

During cutting procedures, forced coagulation and spray coagulation, the unavoidable electric arcs between an active electrode and the tissue nevertheless have the effect that a portion of the high-frequency alternating current is rectified, from which more or less strongly modulated, low-frequency current components result which stimulate electrically stimulable structures such as nerves and muscles.

This can result in more or less strong spasms or muscle contractions.

WARNING!

When using high-frequency surgery on electrically stimulable structures, contractions of the affected muscles must be taken into account. This can occur, for example, during endoscopic operations in the urinary bladder in the vicinity of the obturator nerve and during operations in the area of the facial nerve.

3.4 Cardiac pacemaker

For patients with implanted cardiac pacemakers or pacemaker electrodes, irreparable damage to the pacemaker and disturbance of the pacemaker function, which can lead to ventricular fibrilation, must be reckoned with.

3.5 Danger of explosion

High-frequency surgical units always generate sparks during operation on the active electrode. For this reason, it is necessary to make certain during interventions that anesthetics, degreasers and disinfectants are neither flammable nor explosive. They should at least have evaporated completely before switching on the high-frequency surgical unit and be removed from the area of spark formation.

3.6 Interference with other electronic equipment

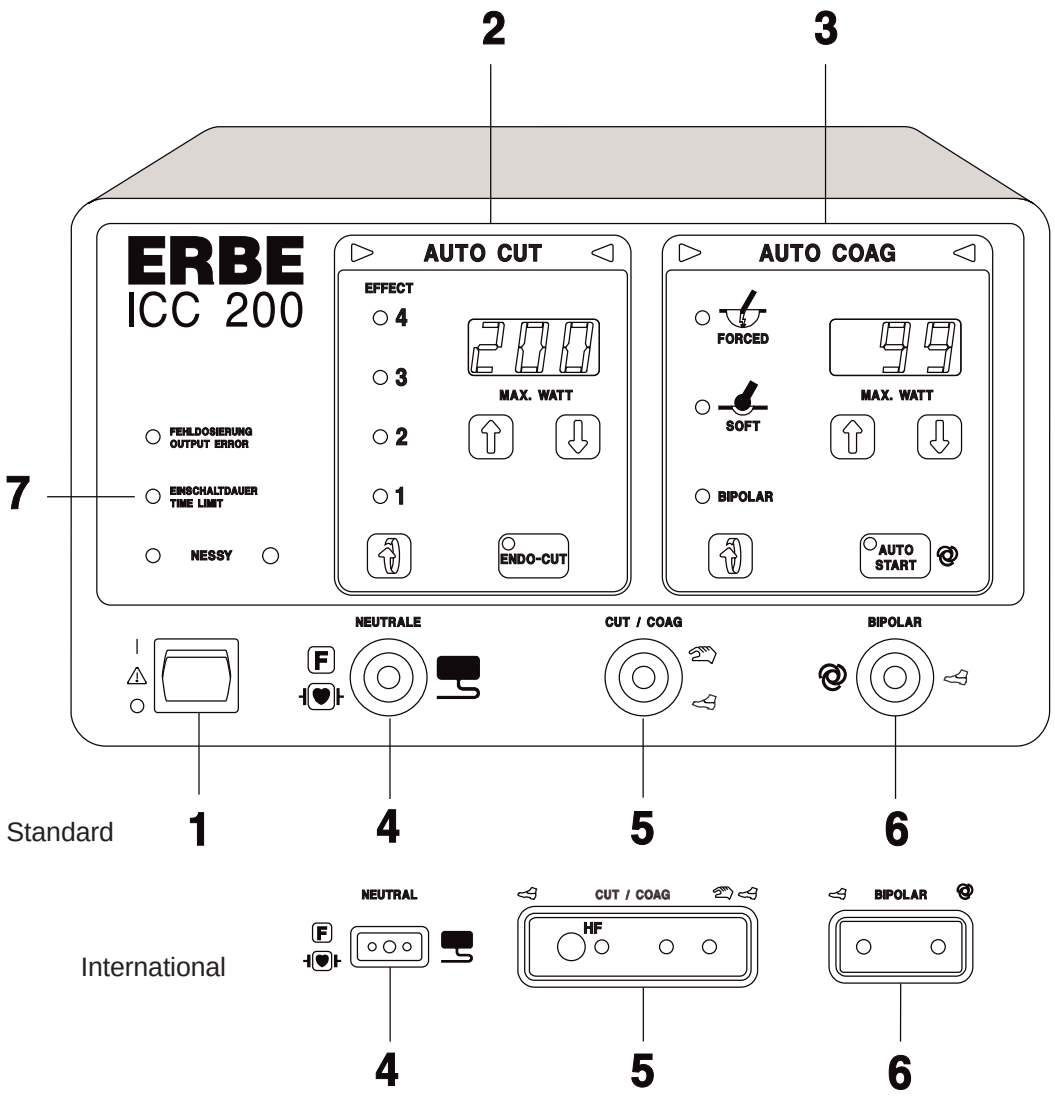
High-frequency surgical units normally generate high-frequency electrical voltages and currents which can interfere with other electronic equipment.

When installing or arranging sensitive electronic equipment in the operating room, this problem should be taken into consideration. In principle, sensitive electronic equipment should be set up as far as possible from the high-frequency surgical unit and particularly from the cables providing HF current. In addition, the cables providing HF current, which act like broadcast antennas, should not be unnecessarily long and should never be positioned parallel or too close to cables from sensitive electronic equipment.

The unit has been fitted with a special generator in consideration of the disturbance of sensitive electronic equipment, which generates a relatively low interference level as compared to conventional high-frequency surgical units.

3.7 Portable and mobile communication equipment HF

ATTENTION: Portable and mobile communication equipment HF can influence the device.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ICC 200
AUTO CUT
EFFECT
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1
200
MAX. WATT
ENDO-CUT
AUTO COAG
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SOFT
BIPOLAR
99
MAX. WATT
AUTO START
FEHLDOSIERUNG
OUTPUT ERROR
EINSCHALTDAUER
TIME LIMIT
NESSY
7
NEUTRALE
CUT / COAG
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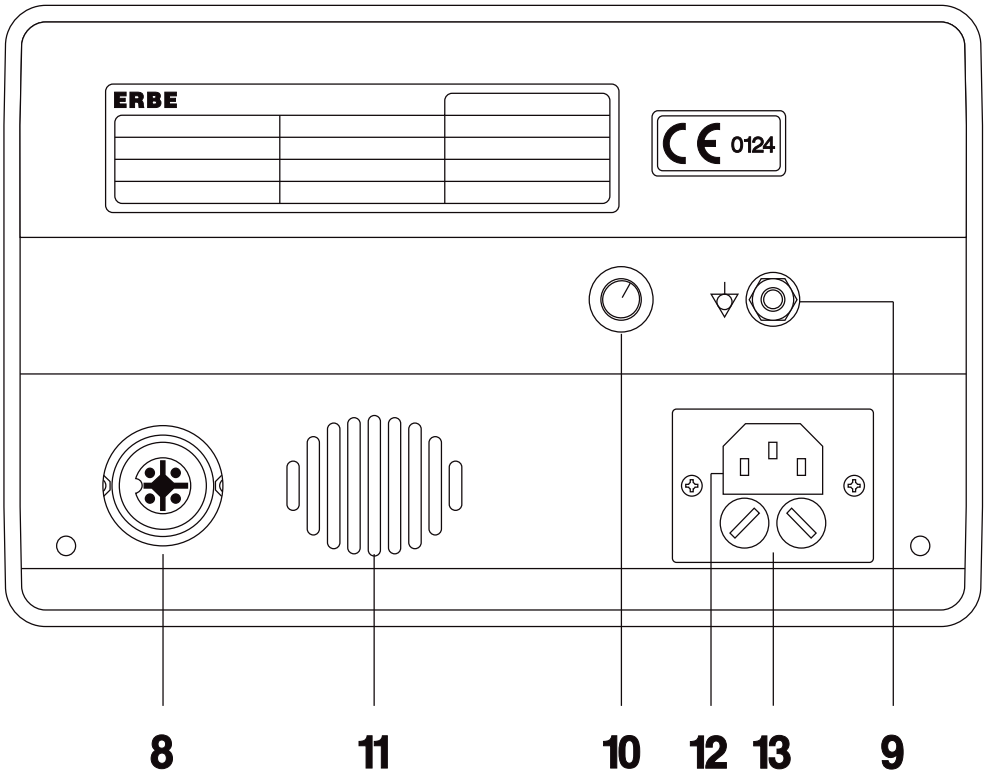
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4 DESCRIPTION OF THE HIGH-FREQUENCY SURGICAL UNIT

4.1 General description

Cutting with automatic control of the HF voltage (Auto Cut)

The ERBOTOM ICC is equipped with automatic open and closed loop control systems which control and regulate the parameters relevant to the cutting quality so that each respectively selected cutting quality is guaranteed to be reproducible and constant.

Adjustable power limitation in the cutting mode

Since the ICC units are equipped with automatic control of the HF voltage in the cutting mode, a power setting in regard to cutting quality is not required. The adjustable power limitation is primarily intended to guarantee the safety of the patient from unintentional thermal tissue damage, and to protect fine cutting instruments, such as fine needle electrodes, from destruction due to overly high HF currents if these come in contact in activated condition with other metallic instruments. The latter, for example, is a risk during laparoscopic operations. This adjustable power limitation must not be confused with the power setting for conventional high-frequency surgical units, where the cutting quality is directly dependent upon the power setting.

PPS (Power Peak System)

The initial incision phase can represent a special problem during an incision, particularly if the cutting electrode is firmly pressed against the tissue to be cut before activating the HF generator, so that the cutting electrode has a relatively large-surface, and therefore low-resistance, contact. This is the case, for example, for TUR and for endoscopic polypectomy. In such cases, the HF generator must provide higher-than-normal power so that the initial incision can proceed without delay, for otherwise a very large coagulation necrosis may result at the cutting location. The ICC is equipped with an automatic power control which recognizes low-resistance loads and controls the HF generator in such a way that it briefly provides enough power so that the HF voltage, i.e. the intensity of the electric arc, required for the set cutting quality is ensured even for a low-resistance load. Thanks to this device, the average power can be limited to relatively small quantities, which corresponds to an improvement in protection from unintentional thermal tissue damage.

ENDO CUT

A further special problem during endoscopic operations, for example during polypectomy and papillotomy, consists in the fact that the electrodes used for cutting, for example polypectomy loops and papillotomes, must be guided on long wire pulls through narrow working channels on flexible endoscopes, and therefore the operator has no direct control over the cutting procedure. However, particularly for polypectomy and papillotomy, a controlled incision is a requirement in preventing complications. An incision that is too fast can lead to bleeding of the cut edges due to lack of sufficient coagulation. An incision that is too slow can cause thermal damage, for example to the intestinal wall.

For units equipped with a special cutting control (ENDO CUT), fractionation automatically occurs in such a way through the incision that alternating short, automatically arc-controlled cutting intervals with defined pause intervals result. In this way, for example, a polypectomy loop cannot cut through a polyp at just any speed. The cutting speed and the degree of coagulation for the cut edges is more uniform. ENDO CUT is additionally supported by PPS.

It is activated by footswitch.

Soft coagulation

Soft coagulation can be activated by key or pedal.

Forced coagulation

Forced coagulation is advantageous if an efficient hemostasis is to be achieved with relatively small-surface electrodes, such as TUR resection loops.

Adjustable power limitation in the various coagulation modes

For the ERBOTOM ICC units, the surgically relevant coagulation qualities, i.e. the coagulation effects Soft Coag., Forced Coag. and Bipolar Coag., are delimited by definition from one another and selectable by the press of a key. Nevertheless, the intensity of the different effects can be varied by power limitation.

Operating mode for Argon Gas Coagulation

For units equipped with the Argon Coag operating mode, the ERBOTOM ICC 200 supplies a pulsating HF voltage with peak values up to 4,000 V_p for Argon Gas Coagulation.

Bipolar coagulation

In this coagulation mode, the HF voltage is, similar to Soft coagulation, automatically and constantly controlled, and its peak value always remains lower than 200 Vp, so that the current density and thus the coagulation effect is, for the most part, independent of the effective contact surface between the coagulation electrode and the tissue, provided the effective contact surface is not too large relative to the currently set power limitation.

The adjustable power limitation serves the purpose of protecting fine bipolar coagulation instruments, such as pointed bipolar coagulation forceps, from being thermally destroyed in case of a short between the two forcep tips.

The footswitch or Auto Start is used for activation.

In the Auto Start mode, the HF generator is automatically activated if both poles of the bipolar coagulation instruments used contact electrically conductive tissue simultaneously. Auto Start can occur either immediately at the moment of contact with the tissue or more or less temporally delayed. With immediate activation, it is possible to work very quickly, especially if several coagulations must be performed one after another. Delayed activation offers the operator the advantage that he/she can prepare and securely grasp the tissue to be coagulated with the bipolar coagulation forceps before the HF generator is automatically activated. Automatic activation of the HF generator only occurs if both poles of the bipolar coagulation instruments contact the tissue uninterruptedly for at least as long as the respectively selected delay lasts. If the contact is interrupted before the respectively selected period of delay is over, the respective period of delay restarts as of the next contact.

4.2 Description of the controls

This symbol, in accordance with EN 60 601-1, is intended to indicate to the user that this unit must only be used on the patient if the user is acquainted with the operation and features of this unit.

The figures set in cursive relate to the ICC illustration for this chapter, or to the function fields in the text.

1 Power switch

Using this power switch, the unit is switched on and off.

Each time after being switched on, the unit automatically proceeds with various performance checks. If an error in the unit or in the accessories is recognized here, a warning signal sounds and the determined error is indicated by a corresponding error number. (See Chapter 8.1, Automatic performance checks after switching on the unit). If no error is determined, the unit is ready to operate.

If the unit was switched off for less than approx. 15 seconds, all settings for the program used before switching off appear after the automatic performance check on the front panel, and the unit can be immediately reactivated. This is advantageous if, for example, the power supply briefly fails.

If the unit was switched off for longer than approx. 15 seconds, the basic setting of the program used before switching off appears after the automatic performance check on the front panel, whereby all relevant visual displays continue to blink and the unit cannot be activated until any key on the front panel is briefly pressed as confirmation that this program should be used. Then the relevant displays are continously illuminated and the unit can be activated using the available settings. These settings can be changed or adapted to the current requirements at any time. However, other programs can be selected as well.

2-3 Function fields

The AUTO CUT and AUTO COAG function fields can be adjusted separately from one another, although not activated simultaneously for reasons of safety.

WARNING!

Function fields that are not used may be switched off completely to prevent unintentional activation. To do this, the power limitation must be set down so far in the corresponding function field until a beep is heard and " —" appears on the digital display. The corresponding function field cannot be activated in this condition.

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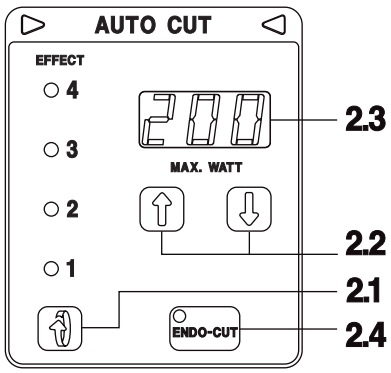
2 AUTO CUT function field



All parameters can be set in this function field that are relevant to cutting:

2.1 Setting of the coagulation EFFECT when cutting

Here the required cutting quality in regard to the coagulation effect on the cutting edges can be adjusted.
Level 1 corresponds to minimum coagulation effect.
Level 4 corresponds to maximum coagulation effect.

2.2 Setting the power limitation

The HF power output can be limited in one watt steps from 200 watts to 1 watt. If display 2.3 shows " —" , the Auto Cut mode is switched off.

2.3 Display of the set power limitation in watts

This display shows the currently set power limitation

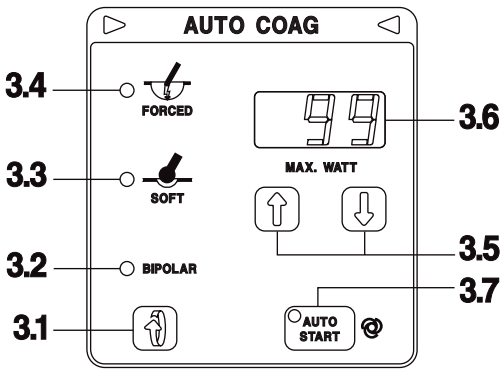
2.4 ENDO CUT

is a cutting mode by which the cutting procedure is automatically fractionated. In this way, for example during endoscopic polypectomy or papillotomy, the cutting electrode is prevented from cutting through the tissue too quickly. The ENDO-CUT key is only active on models ICC 200 E and ICC 200 EA.

Activation of monopolar cutting

can be done using either the yellow key on the electrode handle or the yellow pedal on the footswitch. Activation is visually signaled by continuous illumination of the triangle symbols in the upper part of the CUT function field and also acoustically signaled. Monopolar cutting instruments are connected to the CUT/COAG socket.

3 AUTO COAG function field



All parameters can be set in this function field that are relevant to coagulation:

3.1 Selection of the coagulation mode

By pressing this key, one of the following coagulation modes can be selected:

3.2 Bipolar coagulation with or without AUTO START

3.3 Soft coagulation

3.4 Forced coagulation (Check the version. See Chapter 6.12)

3.5 Power limitation

The HF power output can be limited in BIPOLAR, SOFT and FORCED COAG mode in 1 watt steps from 120 watts to 1 watt. The HF power output can be limited in ARGON COAG mode from 99 watts to 1 watt. If the display shows "—", the Auto Coag mode is switched off.

3.6 Display of the set power limitation in max. watt

3.7 AUTO START

ON / OFF for bipolar coagulation. The AUTO START function can only be switched on with the setting AUTO COAG BIPOLAR.

WARNING!

Only use Auto Start if unintentional contact of tissue with the coagulation instrument can be safely avoided. For endoscopic interventions, such as laparoscopy, pelviscopy or thoracoscopy, Auto Start should not be used because unintentional contact of the coagulation instrument with tissue cannot be safely avoided here.

In some countries the ICC units are supplied with the AUTO START function deactivated. This may also apply in your case. If you nevertheless wish to use the AUTO START function, please consult your local ERBE branch office. You will find the address on the last page of the Instruction Manual. Technical Service will activate the AUTO START function for you on request.

The AUTO START key has no function on the ICC 200 No. 10128-027, 10128-028, 10128-058!

ARGON PLASMA COAGULATION

Set AUTO COAG to FORCED. Press the selection key again. The display shows: A.60. This means: APC mode, power limitation 60 W. The APC mode is only available on the ICC 200 EA.

ACTIVATION

Soft and Forced coagulation can be activated by the blue key or the blue pedal. Bipolar coagulation can be activated by the blue pedal or by Auto Start. Argon Plasma coagulation can be activated via a blue pedal. Activation is signaled by illumination of the triangle symbols in the AUTO COAG function field as well as acoustically.

4 Connecting socket for neutral electrodes

For monopolar cutting and/or coagulation, a suitable neutral electrode must be used that must both be connected to the unit as well as carefully applied to the patient.

The ICC is equipped with a Neutral Electrode Monitoring System (**NESSY**) which automatically monitors the electrical connection between the neutral electrode and the unit as well as application of the neutral electrode on the patient. The latter only then however if neutral electrodes with two contact surfaces are used.

WARNING!

If single-surface neutral electrodes are used, NESSY only monitors the electrical connection between the neutral electrode and the unit, but not the application of the neutral electrode on the patient.

The pictograms beside the connecting socket for neutral electrodes have the following explanation:

Neutral electrode in general

The unit conforms to the requirements in EN 60 601-2-2, Sec. 19.101b, according to which the applied part of the unit is insulated to ground potential compatible to HF technology.

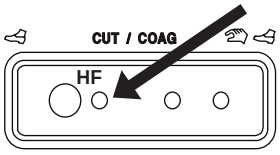
The ICC conforms to the requirements of Type CF in accordance with EN 60 601-1. In addition, this pictogram indicates, in accordance with EN 60 601-2-2, that the neutral electrode can remain applied to the patient during defibrillation.

5 Connecting socket for monopolar cutting or coagulation instruments

Electrode handles with or without fingerswitches can be operated at this connecting socket. Other instruments, such as electrodes for rigid or flexible endoscopes for endoscopic operations, can be connected to this connecting socket. Attention must be paid here to the correct plug type. This connecting socket can be activated via fingerswitch or the pedals of a footswitch.

Protection of the unit against damage: Use of the monopolar receptacle module (international)

IMPORTANT: If you use a connecting cable with a monopolar 4 mm dia. connector, you may only plug the connector into the receptacle labelled HF. The correct receptacle is marked with an arrow on the illustration. If you use a different receptacle, the unit will be damaged.



6 Connecting socket for bipolar coagulation instruments

Bipolar instruments can be connected to this connecting socket. The bipolar coagulation mode is activated via pedal or Auto Start.

CAUTION!

When using pointed bipolar coagulation forceps, the tips can be thermally damaged due to electric currents that are too high. To prevent this, it is recommended that the power limitation be set as low as possible and/or make certain that the tips of the bipolar coagulation forceps do not touch one another.

7 Safety field

High-frequency surgical units of the ERBOTOM ICC series are equipped with various safety devices to protect the patients and users.

8 Connecting socket for a dual-pedal footswitch

A dual-pedal footswitch can be connected to this connecting socket. When using a dual-pedal footswitch, the AUTO CUT function field can be activated with the yellow pedal and the AUTO COAG function field can be activated with the blue pedal.

9 Terminal for potential equalization

For this, see Chapter 6.4 “INSTALLATION“.

10 Volume of the acoustic signal

The volume of the acoustic signals can be set using this knob.
This does not apply to warning signals, which must always be sufficiently loud.

WARNING!

An important purpose of this acoustic signal is to protect the patients and personnel from burns due to unintentional activation of the high-frequency generator (for more information, see Chapter 3.1.2, Unintentional activation of a high-frequency generator).

11 Loudspeaker for acoustic signals

Always set up the instrument in such a way that acoustic signals are easily heard from this speaker.

12 Power connection

This high-frequency surgical unit must only be connected via the power cord supplied by the unit manufacturer or one of these of equal quality, which bears the national test symbol, to correctly installed hospital grade power sockets. Here, for reasons of safety, no multiple sockets or extension cords must be used if possible. If their use is unavoidable, they must be equipped with a correctly functioning grounded connector.

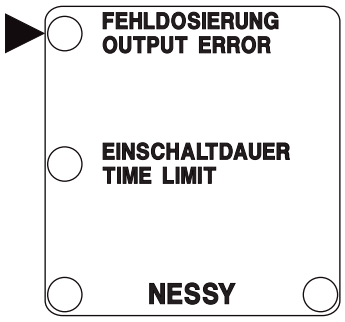
13 Power fuses

The unit is secured with two fuses. If these fuses fail, an authorized technician should inspect the unit for possible errors before putting back into operation.

4.3. Description of the safety features

The ICC 200 is equipped with the following safety features:
4.3.1 OUTPUT ERROR = Automatic monitoring of unit-related output error
4.3.2 TIME LIMIT = Automatic monitoring of the time limit
4.3.3 NESSY = Neutral Electrode Safety System
4.3.4 Protection against operating error

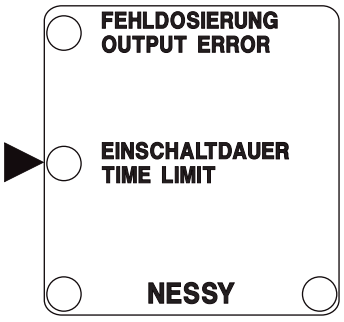
4.3.1 Unit-related output error



The ICC is equipped with automatic monitoring of the HF output parameters, which monitors deviations in the actual value from the set value for the currently set HF output parameters and produces a warning signal and/or switches off the HF generator if the deviation is so large than the required quality of the respective effect (cutting or coagulation) is no longer ensured. In case of deviations or absence of the required effect, display of a unit-related output error allows the operator to immediately check whether the defect is caused by the unit or not.

Deviations in the HF output parameters from the currently set HF output parameters on the ICC can only result from loads which have too low a resistance, e.g. coagulation electrodes that are too large, a short circuit between the active and neutral electrode, or due to an error in the unit.

4.3.2 Time limit



With normal use, a high-frequency generator is only activated briefly for performance of an incision or a coagulation by fingerswitch, pedal or AUTO START. This generally lasts only a few seconds.

Through an error in the unit, in the accessories or in use, the high-frequency generator can be switched on unintentionally. To prevent greater damage due to unintentional activation of the high-frequency generator, the ICC is equipped with a monitor which automatically monitors the time limit on the high-frequency generator. Once a predetermined maximum time limit has been exceeded, this monitor generates a visible signal. If the high-frequency generator is then not switched off, the generator additionally produces an acoustic signal and automatically switches the HF generator off. The high-frequency generator can however be restarted at any time, whereby the time limit is also monitored anew. In this way, greater damage due to unintentional activation of a high-frequency generator for undeterminably long times is avoided.

Custom adaptation of the maximum time limit

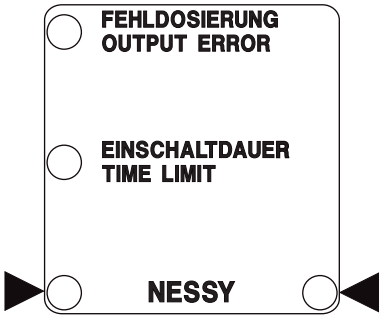
In consideration of the risk of thermal tissue damage due to unintentional switching on of an HF generator, an unintentionally switched-on HF generator should be switched off again as soon as possible automatically. Since the unit cannot automatically distinguish between intentional and unintentional switching on of an HF generator, the automatic switching off of an HF generator must not occur too quickly, because this would hinder the operator during cutting and/or coagulation. Since the risk of thermal tissue damage varies greatly among the various operating modes, the ICC can adapt and store the maximum time limit for each operating mode and in each storable program via the Test program no. 10 of at least 3 sec. to a maximum of 900 sec. (For instructions, see Chapter 6.11).

WARNING!

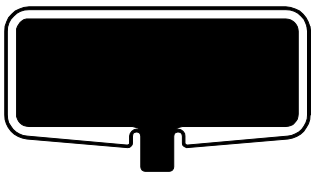
For reasons of safety, a change in the automatic limitation of the maximum time limit must only be made if all users of this unit are informed properly and in good time about this change.

In addition, a change in the automatic limitation of the maximum time limit must be properly documented, for example in the medical product logbook of the respective unit.

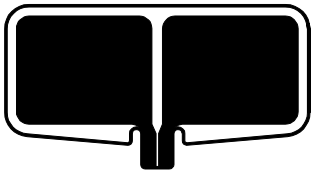
4.3.3 NESSY



The units in the ERBOTOM ICC model series are equipped with a Neutral Electrode Safety System (NESSY), which monitors both the electric connection between the unit and neutral electrode as well as the correct application of the neutral electrode on the patient.



When using neutral electrodes with only one contact surface, only the electric connection between the unit and neutral electrode is automatically monitored. If this connection is sound, the green NESSY signal (LED) is illuminated and all operating modes can be activated. If this connection is interrupted, the green NESSY signal (LED) is not illuminated and the monopolar operating modes cannot be activated. If an attempt is made in this condition to activate a monopolar operating mode, the red NESSY signal (LED) is illuminated and a warning signal is heard at the same time.



When using neutral electrodes with two contact surfaces, not only the electric connection between the unit and neutral electrode is automatically monitored, but also the application of the neutral electrode on the patient. Here the electric conductance between the two contact surfaces on the neutral electrode and the skin of the patient is constantly measured automatically and compared with the intensity of the high-frequency current that flows through the neutral electrode.

If the intensity of the high-frequency current is greater than is permissible at the respectively measured conductance, NESSY then produces visual and acoustic warning signals and the operator should only continue to use the high-frequency surgery if an incision or hemostasis has absolute priority. If the measured conductance between the neutral electrode and the patient is too small, monopolar operating modes cannot be activated.

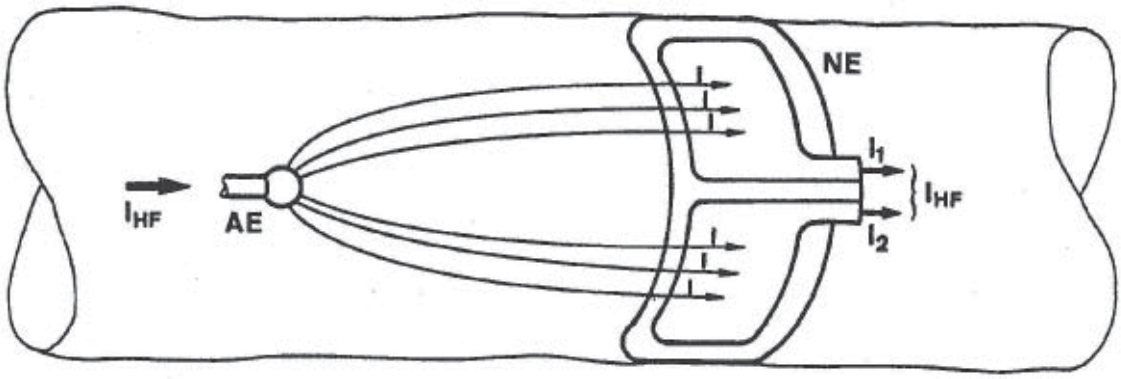
The diversity of neutral electrodes models for high-frequency surgery is very large. The ideal neutral electrode, optimal for all applications, does not yet exist. To ensure the user a large degree of freedom in the selection of the best suited neutral electrodes for his/her purposes, NESSY is a flexible Neutral Electrode Safety System that can be adapted optimally to the neutral electrodes selected by the user. For appropriate advice and adaptation to suit requirements, please contact your local Erbe office (see Chapter Addresses).

WARNING!

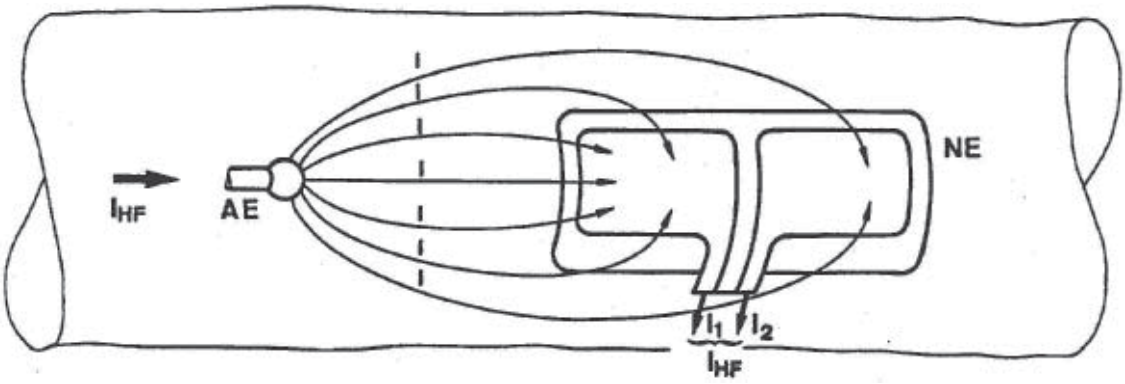
For reasons of safety, a change to NESSY may only be made if it has been properly ensured that all users of this unit are informed in good time about this change. In addition, a change to NESSY must be properly documented.

When using dual-surface neutral electrodes, NESSY also monitors the application direction of the contact surface relative to the direction of current flow. Since the high-freqeuency current is generally not distributed evenly over the contact surface of the neutral electrode, but rather can be greater at the proximal corners or edges to which the current flows than at the distal corners or edges, attention should always be paid during application of neutral electrodes that the current flows toward the long edge.

NESSY compares the intensity of the two partial currents I_1 and I_2 of the high-frequency current I_{HF}, which flow through the two partial surfaces of the neutral electrode. If the partial currents I_1 and I_2 deviate from one another, the red NESSY signal is illuminated. If the partial currents deviate extremely from one another, the red NESSY signal is illuminated and at the same time the NESSY warning signal is heard, and the HF generator is automatically switched off.



Neutral electrode suitable for NESSY - applied correctly



Neutral electrode suitable for NESSY - applied incorrectly

The correct application must be observed not only for divided, but also for undivided neutral electrodes.

NESSY Settings

In the service programs of the unit a technician can perform various NESSY settings according to your requirements. In the following table you can see what effects the settings have on the safety of monitoring.

In the first column you can see the safety level. 1 = maximum safety.

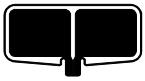
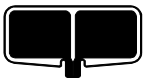
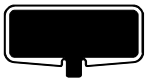
In the second column you can see the return electrode used.

In the third column you can see the setting in the service programs.

In columns 4 - 6 you can see what level of safety is provided by NESSY.

You can achieve maximum safety by using a two-surface return electrode and setting NE.3 or NE.4.

The only difference between settings NE.3 and NE.4 is the alarm tone: 3 times for NE.3, continuous tone for NE.4.

Safety level	Return electrode	Setting in the service programs	Monitoring: connection between unit and return electrode	Monitoring: contact between skin and return electrode	Monitoring: direction of application of the return electrode
1		NE.3 or NE.4 (for two-surface return electrodes)	•	•	•
2		NE.1 (for two-surface or single-surface return electrodes)	•	Limited monitoring, observe warning with NE.1 setting!	Limited monitoring, observe warning with NE.1 setting!
3		NE.1 (for two-surface or single-surface return electrodes)	•		
3		NE.2 (for single-surface return electrodes)	•		

When using a two-surface return electrode and setting NE.1

WARNING!

If there is a short in the connecting cord or in the clip on a two-surface return electrode, the unit can no longer monitor contact with the patient's skin or the direction of application of the contact surface. You get no warning if the electrode becomes detached from the skin and there is a risk of a burn. You get no warning if the direction of application of the contact surface is incorrect.

Checking for a short in the connecting cord

In order to be sure there is no short in the connecting cord proceed as follows:

a) In the case of return electrodes without a permanently connected cord

Switch on the unit. Plug the connecting cord into the socket for the return electrode. The green NESSY signal (LED) must NOT be lit. Only connect the cord to the return electrode when this has been checked.

b) In the case of return electrodes with a permanently connected cord

Switch on the unit. Plug the connecting cord into the socket for the return electrode. The green NESSY signal (LED) must NOT be lit. Only apply the return electrode when this has been checked on the patient.

4.3.4 Protection against operating error

To prevent operating errors, the front panel is designed in such a way that illogical and/or incomplete settings are automatically monitored and signaled.

The female connector beneath the front panel contains all the connecting sockets for the applied part.

These connecting sockets are designed in such a way that only plugs from intended accessories can be inserted (provided that only accessories recommended or supplied by the manufacturer of the unit are used).

Each time after switching on the power switch, an automatic test program is started within the unit which recognizes and signals the following errors in the operating controls for the unit and for accessories connected to the unit:

1. If a key on the front panel is shorted or pressed due to an error when the power switch is switched on, this error is indicated acoustically and by an Error Number after the power switch has been switched on.

2. If a key on the electrode handle is shorted or bypassed at low resistance due to an error (e.g. by moisture in the electrode handle) or pressed while the power switch is switched on, this error is signaled acoustically and indicated by an Error Number after switching on the power switch.

3. If a footswitch contact is shorted due to an error, a pedal sticks or a pedal is pressed while the power switch is switched on, this error is indicated acoustically and by an Error Number.

CAUTION!

Every function field can only then be activated if it has been completely set. If an attempt is made to activate a function field which has not or not completely been set, the unit produces an intermittent acoustic warning signal and indicates this operating error by illumination of the triangle symbols on the corresponding function field.

5 TECHNICAL DATA, SIGNALS, DIAGRAMS

5.1 Technical data

CUTTING / AUTO CUT with automatic voltage control	
HF voltage waveform	unmodulated sinusoidal alternating voltage
Crest factor C, at R_L=500 ohms	C = 1.4 for all settings
Rated frequency	330 kHz
Maximum HF voltage at R_L=∞	600 Vp
Dynamic internal impedance in the rated load range	0 ohms
Cutting quality	4 coagulation effects selectable
Consistancy of 4 coagulation effects	automatically controlled
HF rated power	200 watts at R_L = 500 ohms
HF power limitation	1 to 200 watts in 1 watt steps
Setting the HF power limitation	via up/down keys
Display of HF power limitation	7-segment display, 3 decimal places
Precision of the HF power limitation	+/- 1 digit or +/- 15%
Automatic power control (PPS)	yes
Activation of the cutting mode	via key or via pedal
HF connecting sockets	1

CUTTING / ENDO CUT Applies only to ERBOTOM ICC 200 with Endo Cut	
Automatically arc-triggered, fractionated cutting	
Basic setting	t_{on} = 50 ms, t_{off} = 750 ms

SOFT COAGULATION	
HF voltage waveform	unmodulated sinusoidal alternating voltage
Crest factor C, at R_L = 500 ohms	C = 1.4 for all setttings
Rated frequency of the HF voltage	330 kHz
Peak value of the HF voltage	max. 190 V_p
Constancy of the HF voltage	automatically controlled up to $P_{HFmax.}$
HF rated power	120 watts at 125 ohms
HF power limitation ($P_{HFmax.}$)	from 1 watt to 120 watts in 1 watt steps
Setting of the HF power limitation	via up/down keys
Display of the HF power limitation	7-segment display, 3 decimal places
Precision of the HF power limitation	+/- 1 digit or +/- 15%
Activation of Soft coagulation	via key or via pedal
HF connecting sockets	1

FORCED COAGULATION	
HF voltage waveform	pulse-modulated alternating current (ST generator)
Crest factor C, at R_L=500 ohms	C = 5 at 120 W_{max}, C = 11 at 5 W_{max}
Rated frequency of the HF voltage	1 MHz
Peak value of the HF voltage, Version 1	max. 1300 Vp
Peak value of the HF voltage, Version 2	max. 2300 Vp
Peak value of the HF voltage, Version 3	max. 2300 Vp
HF rated power	120 watts at 350 ohms
HF power limitation	from 1 watt to 120 watts in 1 watt steps
Setting of the HF power limitation	via up/down keys
Stability of the HF power	see diagram Forc. Coag. power via R_L
Display of the HF power limitation	7-segment display, 3 decimal places
Precision of the HF power limitation	+/- 1 digit or +/- 15%
Activation of the Forced coagulation	via key or via pedal
HF connecting sockets	1

ARGON PLASMA COAGULATION Applies only to ERBOTOM ICC 200 with Endo Cut and Argon Coag	
HF voltage waveform	pulse-modulated alternating voltage
Crest factor C, at R_L=500 ohms	C = 8 at 99 W_{max}, C=15 at 5 W_{max}
Rated frequency of the HF voltage	1 MHz
Peak value of the HF voltage	max. 4 kV_p
HF rated power	99 watts at 350 ohms
HF power limitation	from 1 watt to 99 watts in 1 watt steps
Setting of the HF power limitation	via up/down keys
Display of the HF power limitation	7-segment display, 2 decimal places
Precision of the power limitation	+/- 1 digit or +/- 15%
Activation	via key or via pedal
HF connecting sockets	1

BIPOLAR COAGULATION / AUTO BIPOLAR	
HF voltage waveform	unmodulated sinusoidal alternating voltage
Crest factor C, at R_L=500 ohms	C = 1.4 for all settings
Rated frequency	330 kHz
Peak value of the HF voltage	max. 190 V
Constancy of the HF voltage	automatically controlled up to $P_{HFmax.}$
Dynamic internal impedance	0 ohms in rated range
HF rated power	120 watts at 125 ohms
HF power limitation ($P_{HFmax.}$)	from 1 watt to 120 watts in 1 watt steps
Setting the HF power limitation	via up/down keys in 1 watt steps
Display of the HF power limitation	7-segment display, 3 decimal places
Precision of the HF power limitation	+/- 1 digit or +/-15%
Activation of Bipolar coagulation	via pedal or Auto Start
Auto Start delay	from 0 to 10 s via program no. 23
HF connecting sockets	1

SAFETY FEATURES	
Protection class according to EN 60 601-1	I
Type according to EN 60 601-1	CF
Switching of the neutral electrode	Floating Output
Monitoring of single-surface neutral electrodes	Automatic monitoring of the electric connection between neutral electrode and high-frequency surgical unit
Monitoring of dual-surface neutral electrodes	Automatic monitoring a) of the electric connection between the neutral electrode and high-frequency surgical unit b) as well as between the neutral electrode and patient c) of the symmetry of the HF partial currents i_{HF1} / i_{HF2} d) of the HF current I_{HF} dependent on the contact resistance $R_ü$ between the partial surfaces of the neutral electrode
Max. resistance $R_ü$ between the partial surfaces of the divided neutral electrodes	120 ohms ± 20 ohms
Warning signals S_W dependent on I_{HF} and $R_ü$	see Diagram $S_w = f (I_{HF} , R_ü)$
Monitoring of the HF output parameters	HF voltage, HF current, HF power Error display in safety field
Auto. limitation of the max. HF power	adjustable
Auto. limitation of the max. activation time	yes, display in safety field
Auto. function control	self-check after switching on the unit

DOCUMENTATION	
Automatic storage of operating errors	yes
Automatic storage of performance errors	yes
Automatic storage of safety errors	yes

Power connection	
Rated power voltage	240 V / 230 V / 115 V / 110 V / 100 V ± 10 %
Rated power frequency	50 / 60 Hz
Power current	3.0 A at 230 - 240 V / 6.0 A at 100 - 115 V
Power consumption in Standby mode	25 watts
Power consumption at max. HF power	450 watts 690 VA
Current consumption in Standby mode	150 mA at 230 - 240 V / 300 mA at 100 - 115 V
Potential equalization terminal	yes
Power fuses	2 slow burn, 4 A at 230 - 240 V / 8 A at 100 - 115 V

Operating mode	
Intermittent operation	ON time 25 % (e.g. activated for 10 sec. / deactivated for 30 sec.)

Classification according to the EU Directive 93/42/EEC	
Class	IIb

Dimensions, weight	
W x H x D	280 x 152 x 368 mm
Weight	8 kg

Environmental conditions for shipping and storage of the unit	
Temperature	-40°C to + 70°C
Air humidity, relative	10% to 95%

Environmental conditions for operation of the unit	
Temperature	+10°C to + 40°C
Air humidity, relative	30% to 75%, noncondensing

5.2 Visual and acoustic signals

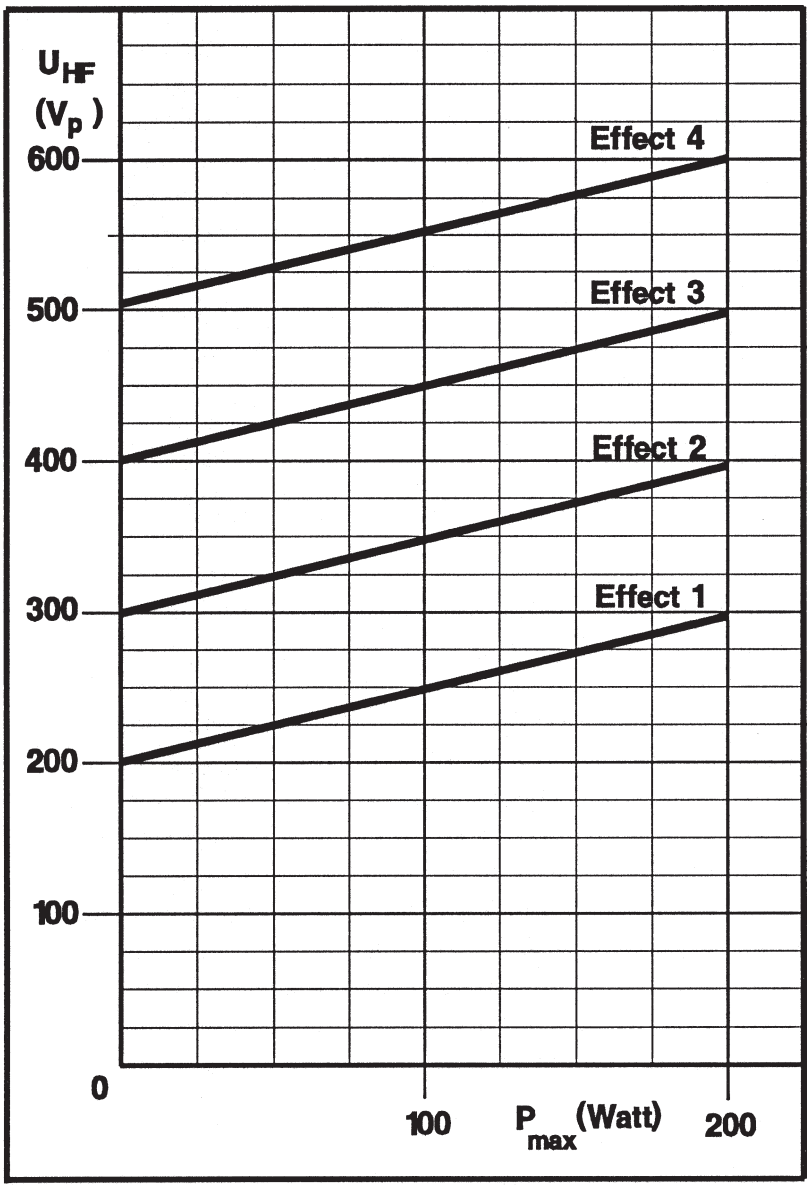
STATUS	visual	acoustic	HF off
Power switch on	•		
Operating error on the front panel	••	••	••
HF generator on	••	••	
Output error	•• red	••	••
Max. activation time reached	•• red		
Max. activation time exceeded too long	•• red	••	••
No neutral electrode connected to the unit	•• red Error No.13	••	••
Single-surface electrode connected to the unit	• green		
Dual-surface neutral electrode connected to the unit and contact resistance between the contact surfaces less than 120 ohms	• green		
Dual-surface neutral electrode not applied to patient or contact resistance between the contact surfaces and patient greater than 120 ohms	•• red Error No.13	••	••
HF current relative to contact resistance between the contact surfaces of a dual-surface neutral electrode and patient too high	•• red Error No.19	•• 4 times	
HF partial currents of the contact surfaces of a dual-surface neutral electrode different	•• red		
HF partial currents of the contact surfaces of a dual-surface neutral electrode too different	•• red Error No.21	••	••
Interruption of the power between unit and neutral electrode or between patient and dual-surface neutral electrode during HF activation	•• red Error No.13	••	••
Activation error	••	••	••
Error message for error recognition during self check	•	•	•

- • These signals are produced regardless of whether the unit is activated or not activated.
- •• These signals are only produced if the unit is activated.

5.3 Diagrams

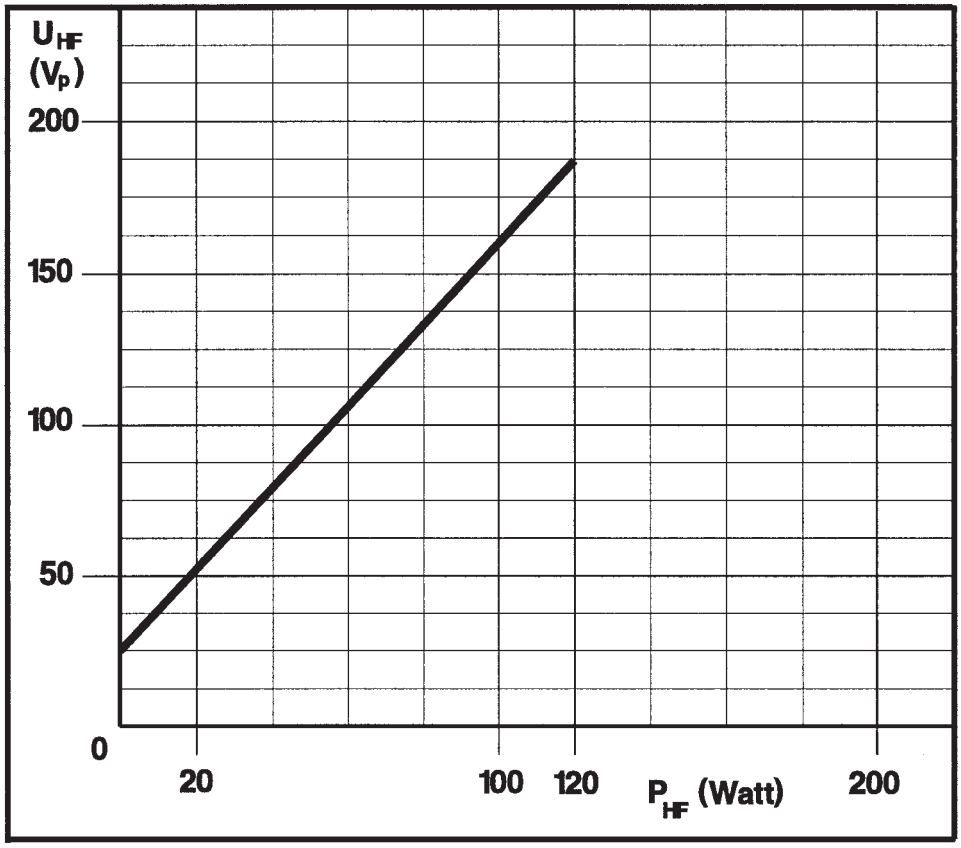
AUTO CUT MODE, Effect 1, 2, 3, 4

Peak value of the HF output voltage U_{HF} at no load, as a function of the power limitation P_{max} for EFFECT 1 to 4.



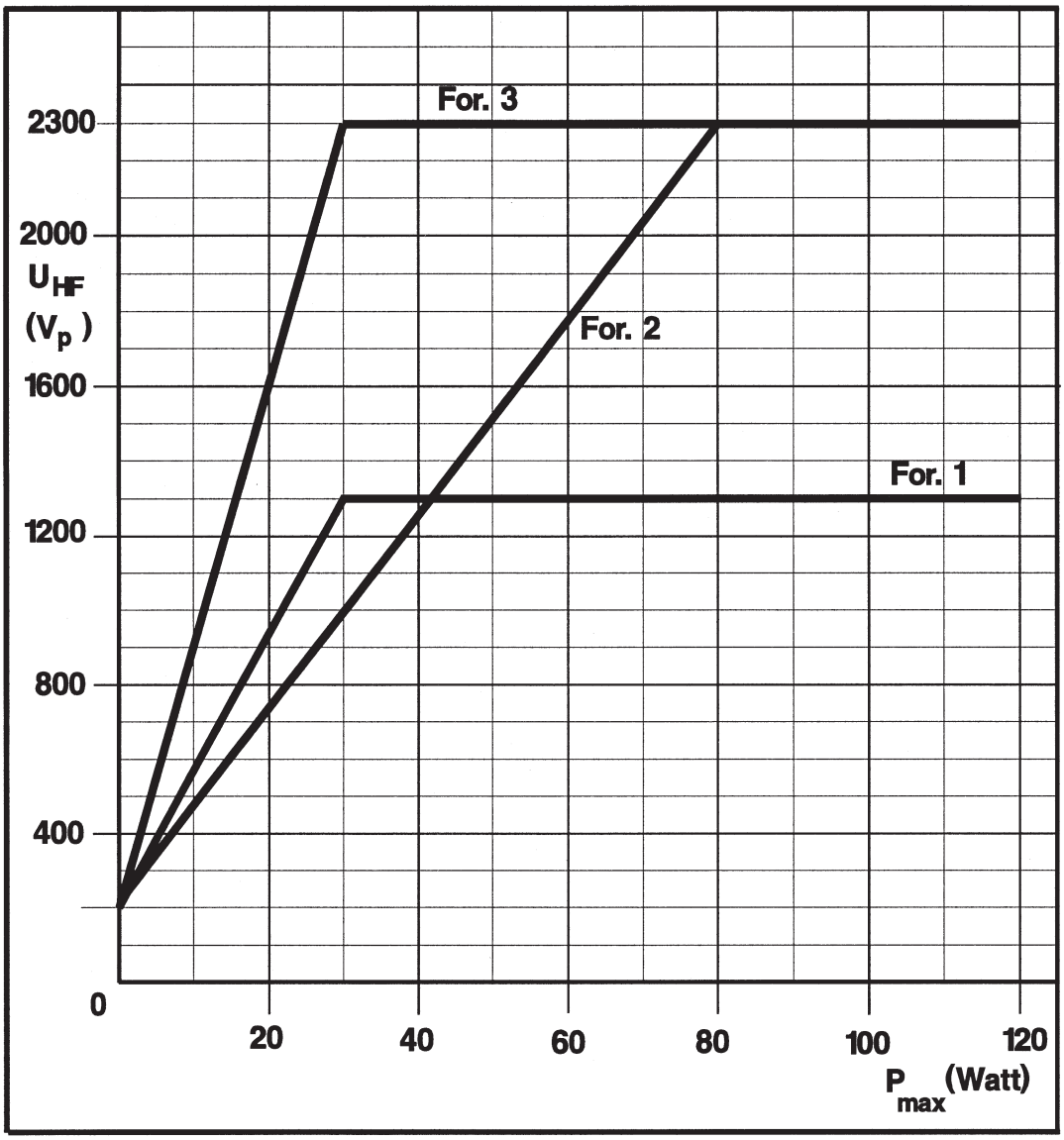
SOFT COAGULATION
AUTO BIPOLAR

Peak value of the HF output voltage U_{HF} at no load, as a function of the power limitation P_{max}.



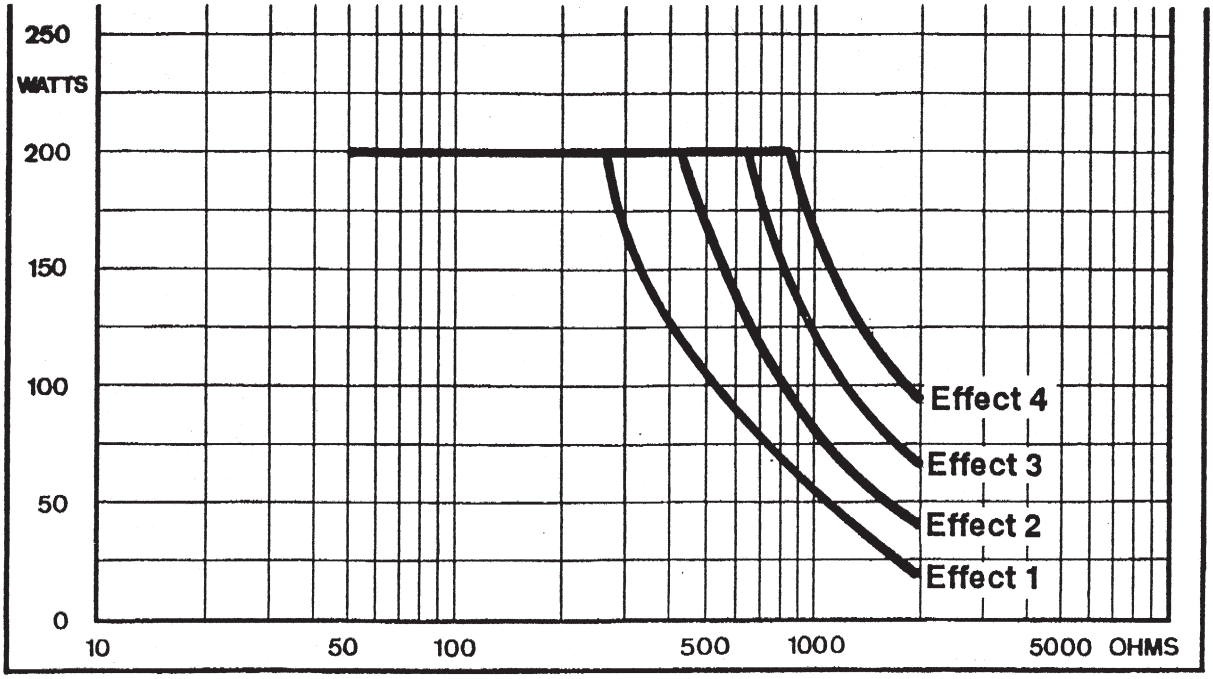
FORCED COAGULATION

Peak value of the HF output voltage U_{HF} at no load, as a function of the power limitation P_{max}.

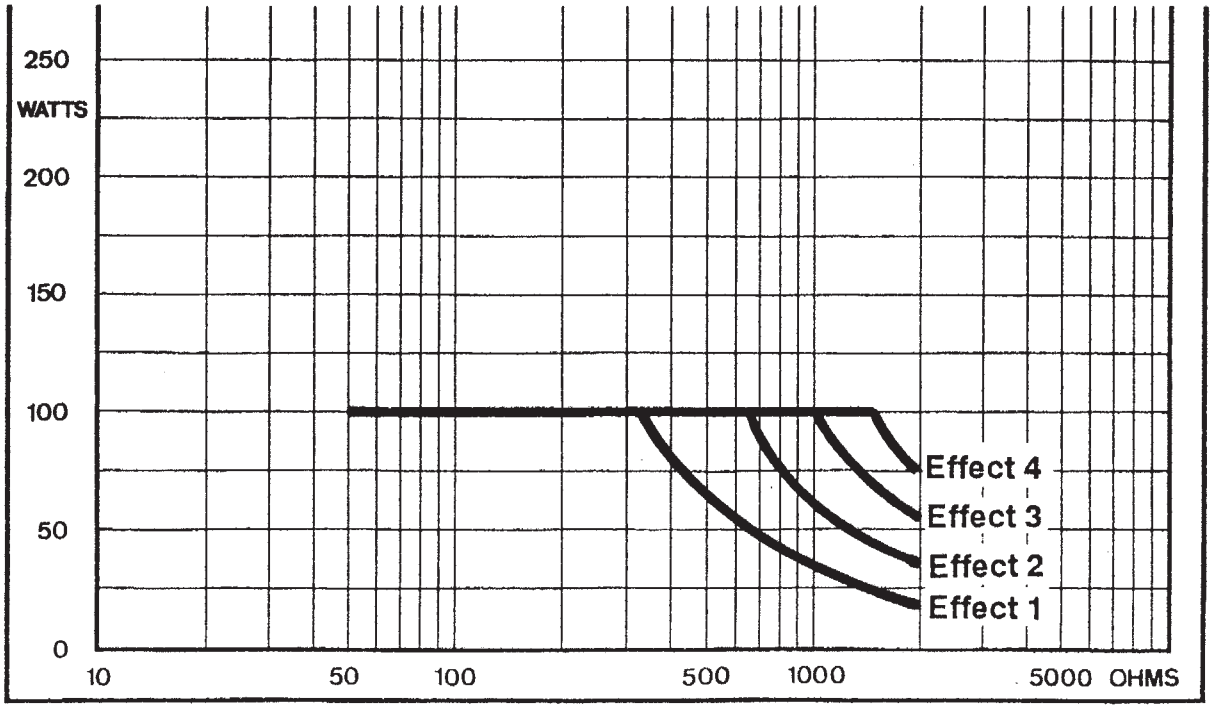


CUT MODE, Effect 1, 2, 3, 4

Power output as a function of load resistance
for power limitation of 200 watts

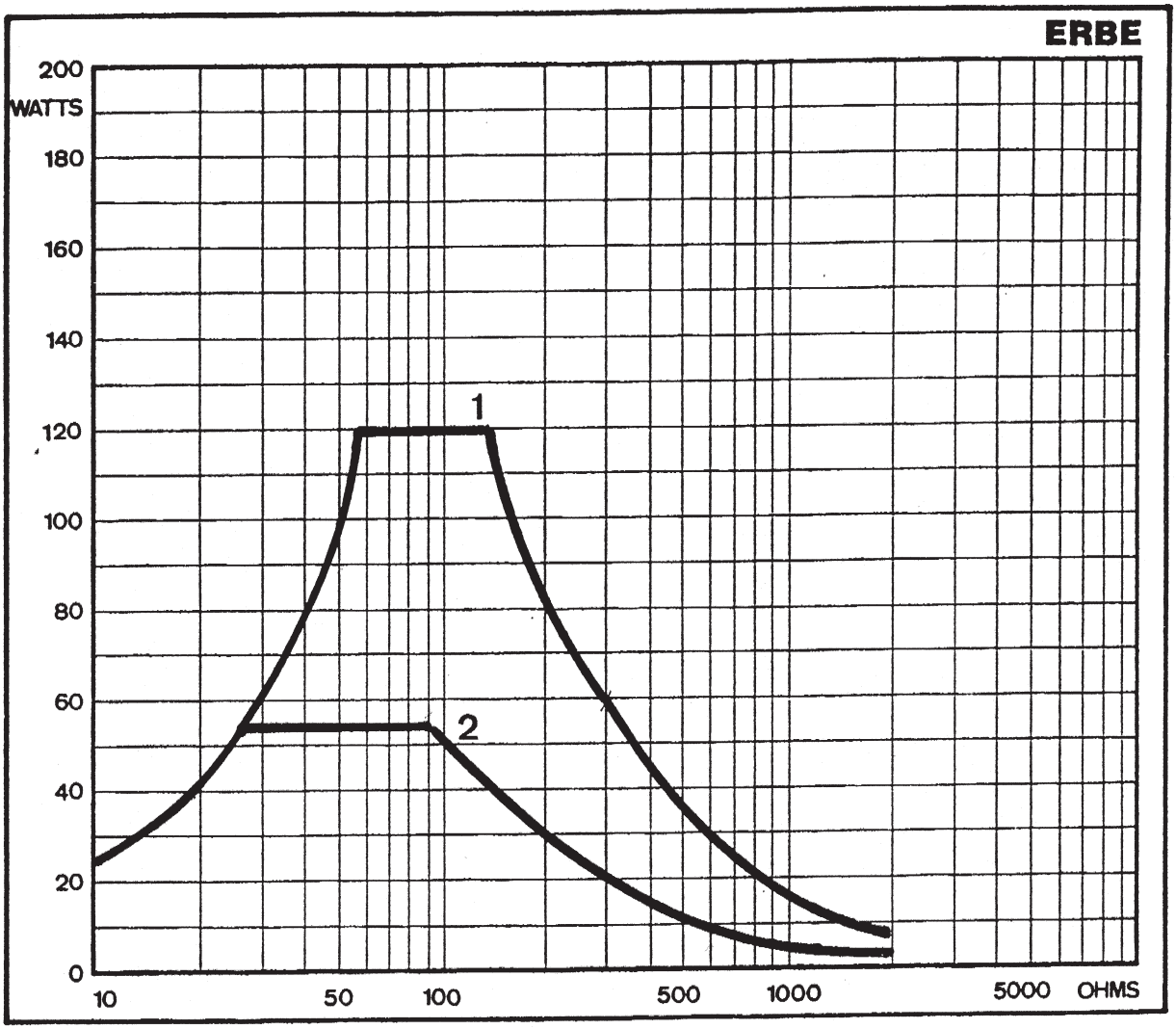


Power output as a function of load resistance for
power limitation of 100 watts



SOFT COAGULATION
AUTO BIPOLAR

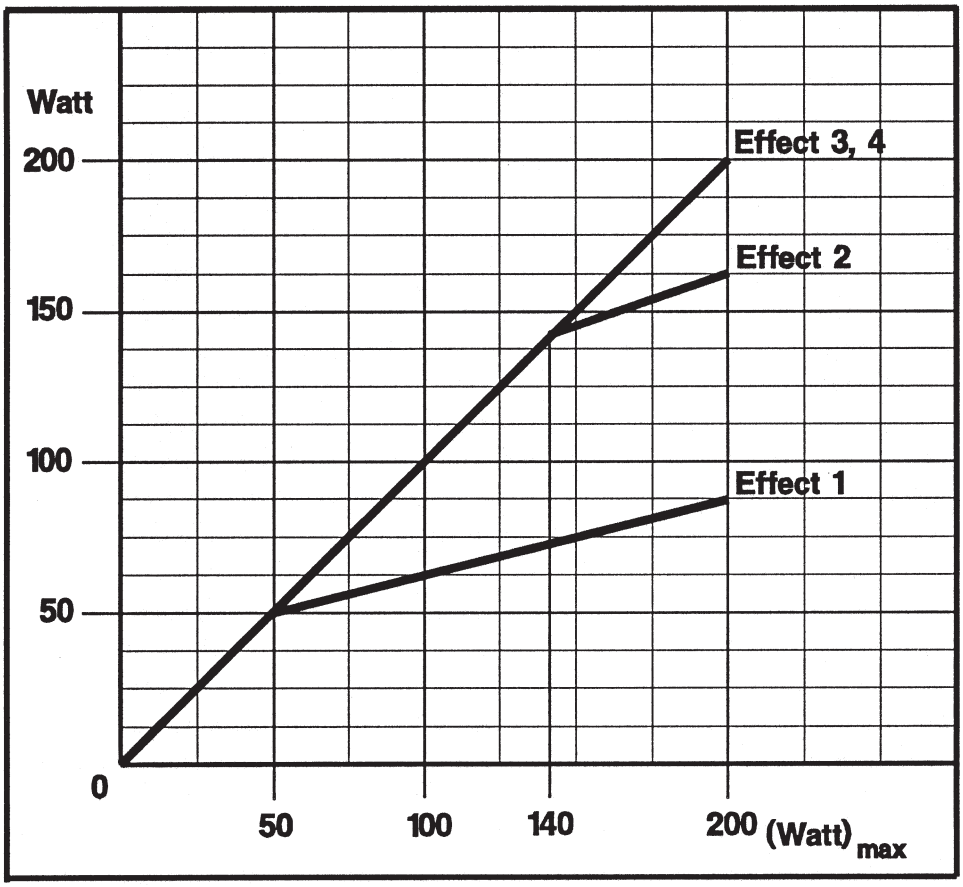
Power output as a function of load resistance for
1) power limitation of 120 watts
2) power limitation of 60 watts



AUTO CUT MODE, Effect 1, 2, 3, 4

Power output as a function of the power limitation

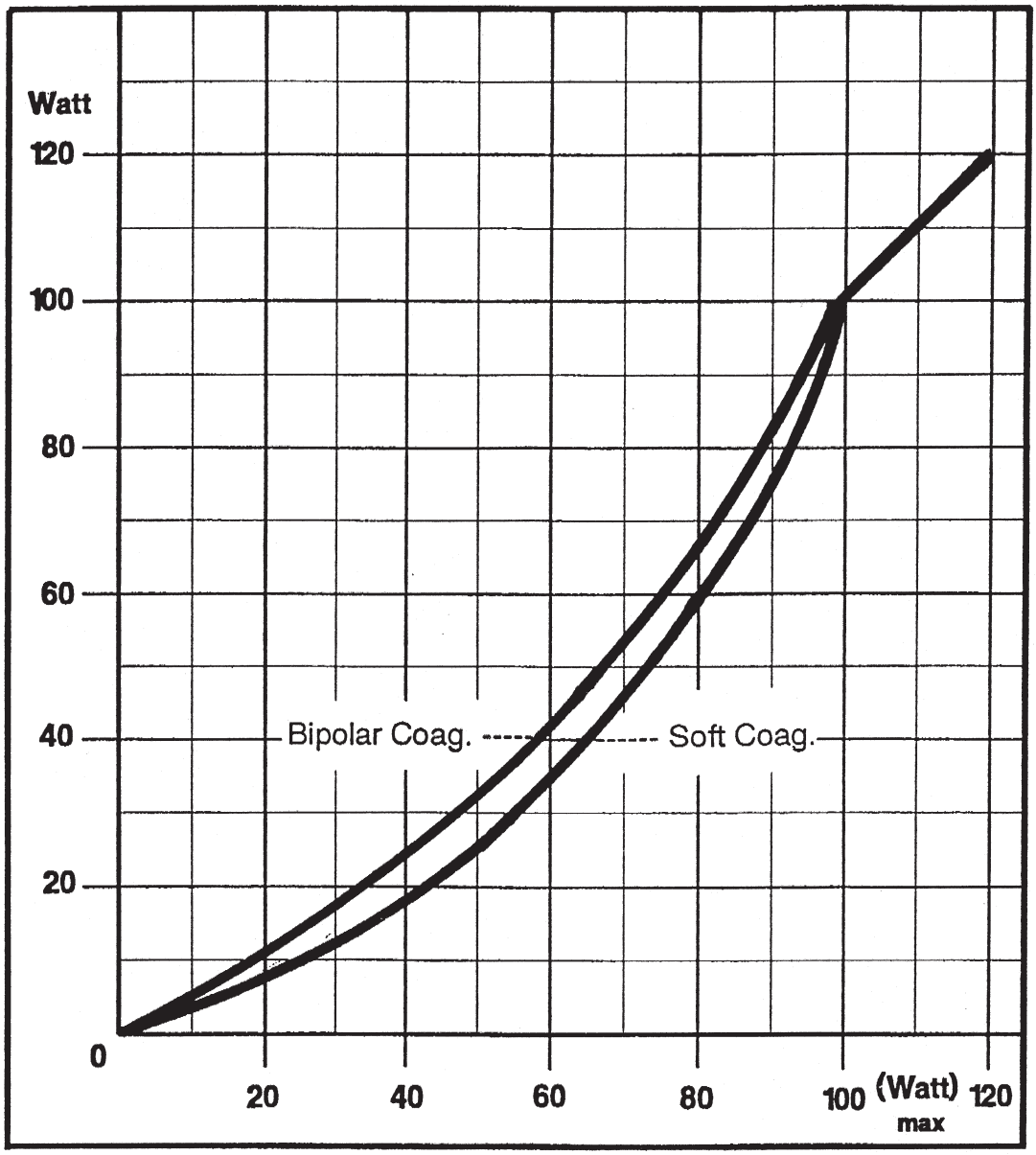
R_L = 500 ohms



SOFT COAGULATION
AUTO BIPOLAR

Power output as a function of the power limitation

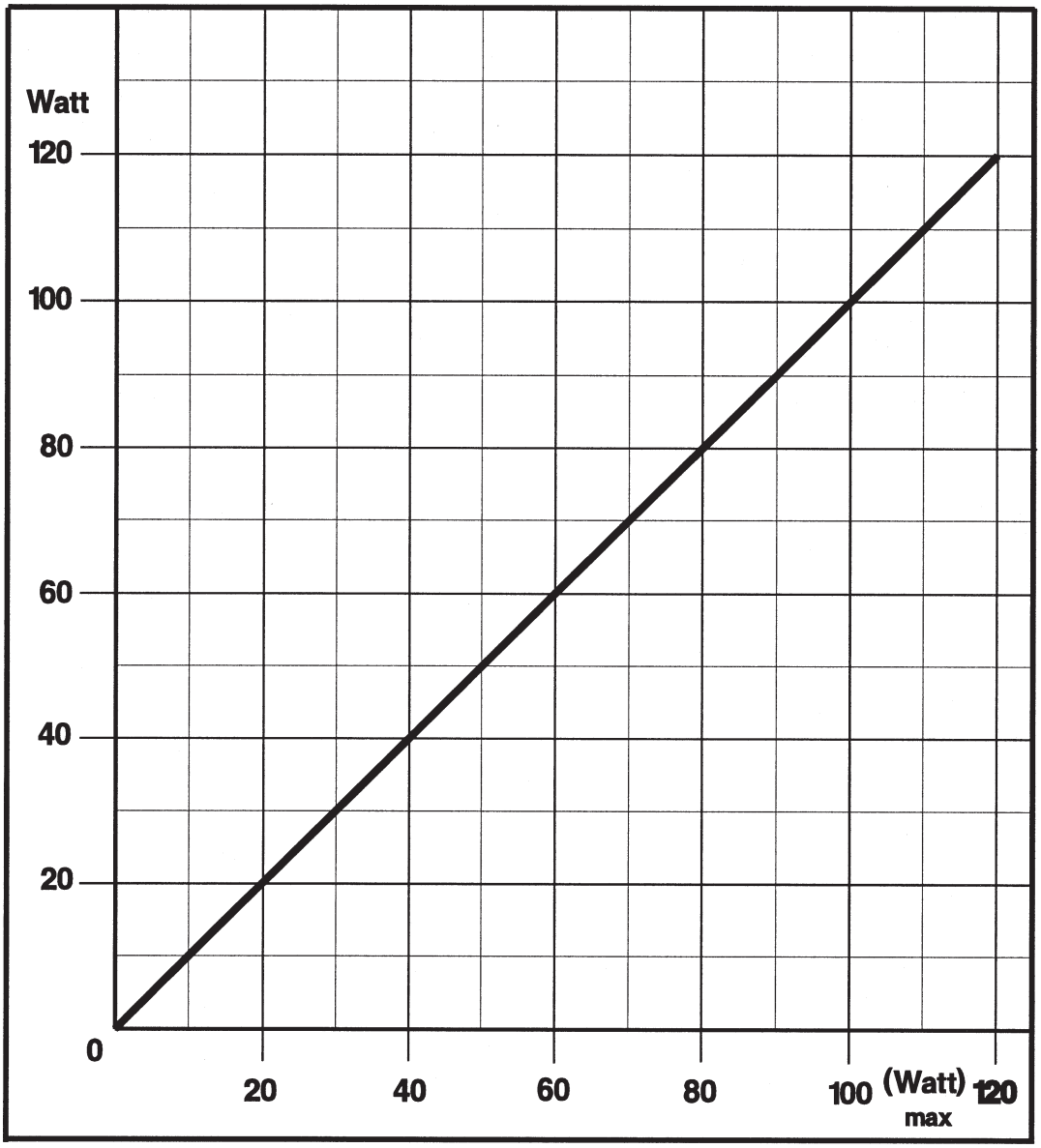
R_L = 125 ohms



FORCED COAGULATION

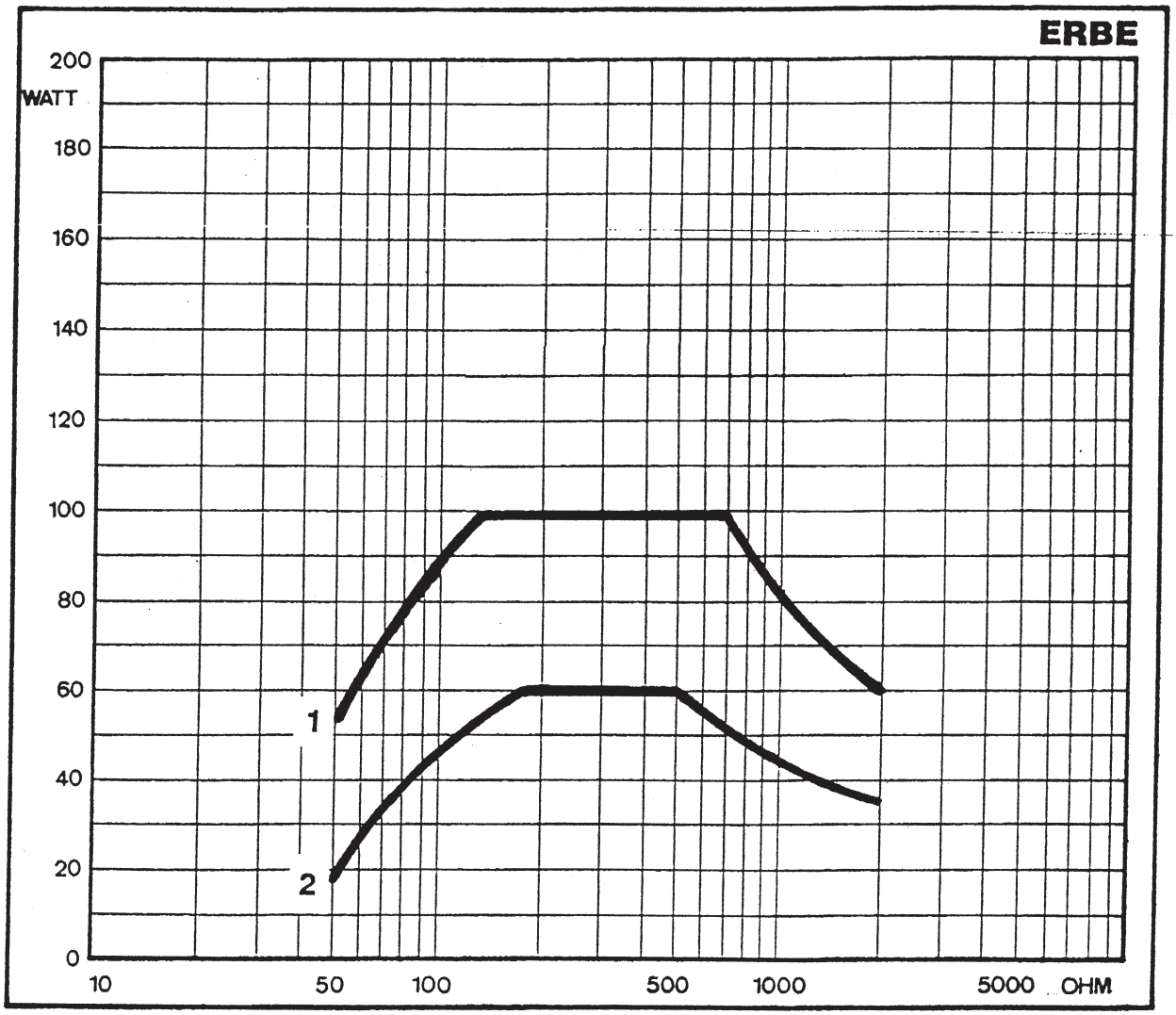
Power output as a function of the power limitation

R_L = 350 ohms



ARGON PLASMA COAGULATION

Power output as a function of load resistance
1) for a power limitation of 99 watts
2) for a power limitation of 60 watts



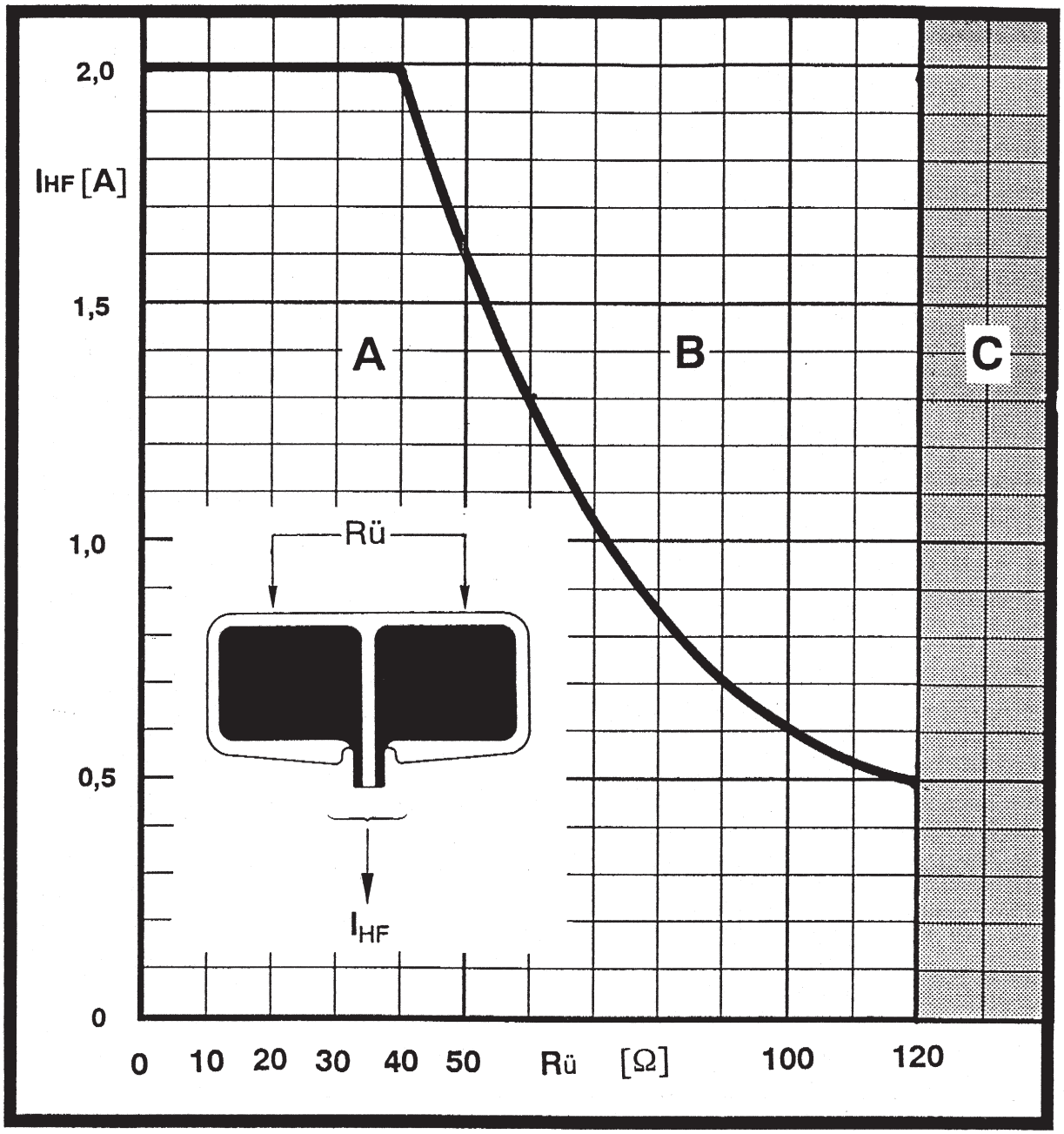
NESSY

Dependence of the warning signals on contact resistance $R_{ü}$ between the two contact surfaces of a divided neutral electrode and the HF current I_{HF} flowing through the entire surface of the neutral electrode:

A = In this range, I_{HF} is sufficiently small relative to $R_{ü}$. No warning signal.

B = In this range, I_{HF} is too large relative to $R_{ü}$. The HF generator can be activated, however a red warning signal and four warning tones are given after each activation of the HF generator. In this condition, the unit must continue to be used only in case of emergency.

C = In this range, $R_{ü}$ is greater than 120 ohms. The HF generator cannot be activated. After every activation attempt, a red warning signal and warning tones are given.



6 INSTALLATION

6.1 Spatial requirements

High-frequency surgery units must only be operated in medically used rooms. The spatial requirements, in regard to electric installation, affect e.g. the grounded conductor system, the ground fault interrupt system, as well as measures for preventing electrostatic charges.

The unit is used in rooms in which personnel can pick up electrostatic charges, for example in rooms with electrically nonconductive floors, thus touching the front panel of the units can lead to a brief illumination of light diodes or seven-segment displays due to discharge of an electrostatic charge. However, this occurrence does not change the settings on the front panel.

6.2 Set-up possibilities in the operating room

ICC model series units can be set up in principle on tables, consoles on ceiling suspensions or wall- mounted arms, as well as on special equipment carts.

6.3 Power connection

High-frequency surgical units must only be connected via the power cord provided by the unit manufacturer or one of equal quality equipped with the national test symbol to a correctly installed hospital grade power socket. Here, no outlet power socket or extension cord should be used if possible for reasons of safety. If their use is unavoidable, these must be equipped with a protective ground in perfect working order. The power outlet must be secured with a fuse with at least 10 A rated current.

6.4 Potential equalization

If necessary, the unit can be connected to the potential equalization of the room. This should prevent low-frequency electrode currents, e.g. low-frequency leakage currents in a defective protective ground system, from endangering the patient.

ICC model series units are equipped with a potential equalization connector on the unit back panel according to DIN 42 801. In this way, the units can be connected via a potential equalization line to a potential equalization terminal at the set-up location.

6.5 Danger of explosion

A potentially explosive atmosphere can result:

- From the release or dissipation of a potentially explosive mixture of anesthetics containing oxygen or nitrous oxide.
- From the use of combustible skin cleansing and disinfection substances.

The spatial extent of the danger zone is defined in the standard IEC 60 601-1 section 37.5. and in explosion safety regulations.

WARNING!

HF surgical units generate electrical sparks, and are thus a potential source of ignition. Set up the HF surgical unit outside the danger area.

WARNING!

Footswitches are also potential sources of ignition. Due to their application, it is not always possible to avoid setting them up in or near to the danger zone. Footswitches must therefore meet the special safety requirements of the "AP Class" in accordance with IEC 60 601-1 and be marked with corresponding labels, if they are set up in the danger zone.

6.6 Protection against moisture

ICC model series high-frequency surgical units are protected against the penetration of moisture in accordance with EN 60 601-2-2 . In spite of this, these units should not be set up in the vicinity of hoses or containers which contain liquids. Liquids should not be placed above or even on the unit. Only those footswitches may be used which are watertight in accordance with EN 60 601-2-2 Sec. 44.6 aa. Only those electrode handles with key switches must be used which conform to EN 60 601-2-2, Sec. 44.6 bb.

6.7 Cooling

ICC model series units must be set up in such a way that free air circulation around their housing is ensured. For that reason, set-up in confined corners, shelves etc. is not permissible.

6.8 HF interferences

High-frequency surgical units intentionally generate high-frequency voltages and currents. It must therefore be taken into consideration during set-up and operation that other electromedical equipment may be subjected to functional interference.

6.9 Combination with other units

If an ICC is to be operated in combination with other units, make certain that the correct functions and the safety of the units are not impaired by this combination.

For combination of an ICC with an Argon Plasma Coagulation unit, the instruction manual for the Argon Plasma Coagulation unit must also be precisely observed.

6.10 Receiving inspection

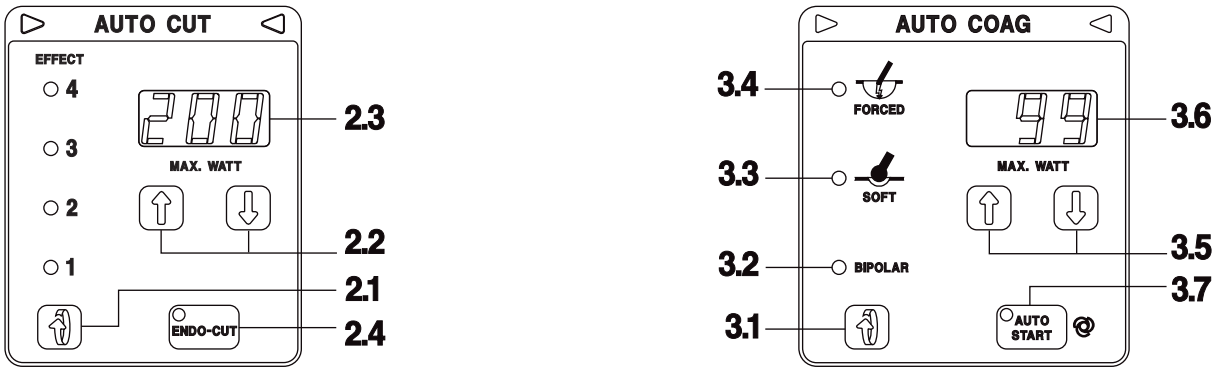
The unit should be checked immediately upon receipt for shipping damage and be subjected to a performance test. In case of damage due to shipping, this must be immediately reported to the shipping agent and a damage report must be filled out to secure the claim for damage compensation. This must include, in addition to the name and address of the recipient, the date of receipt, type and serial number of the unit supplied, as well as a description of the damages.

The unit’s original packaging should be retained during the guarantee period so that the unit can be returned in the original packaging if this becomes necessary.

6.11 Custom adaptation of the maximum time limit

In consideration of the risk of thermal tissue damage due to unintentional switching on of an HF generator, an unintentionally switched-on HF generator should be switched off again as soon as possible automatically. Since the unit cannot automatically distinguish between intentional and unintentional switching on of an HF generator, the automatic switching off of an HF generator must not occur too quickly, because this would hinder the operator during cutting and/or coagulation. Since the risk of thermal tissue damage varies greatly among the various operating modes, units of the ICC model series can adapt and store the maximum time limit for each operating mode and in each storable program via the test program No. 10 of at least 3 sec. to a maximum of 900 sec.

Instructions for custom adaptation of the maximum time limit



1. Call up Test program 10 as follows:

2. Press key 2.1 with the unit switched off and switch on the power.
   Pr. = Program appears in Display 2.3
   The program number, e.g. 1, appears in Display 3.6.

3. By pressing key 3.5 ⇑, program no. 10 is set and

4. by pressing key 2.1, this program is activated.
   The red signal lamp “Time limit“ is illuminated and the respective maximum time limit appears in the displays on the function fields.

5. By pressing the ⇑ or ⇓ key beneath the respective display, the maximum time limit for each function field can be custom adjusted from 3 to 900 seconds.

6. By pressing key 2.1, Test program 10 can be deactivated and the set maximum time limits are stored.

7. It is possible to end the Test mode by switching off the power switch.

WARNING!

For reason of safety, a change in the automatic limitation of the maximum time limit must only be performed if all users of this unit are informed properly and in good time about this change.

In addition, a change in the automatic limitation of the maximum time limit must be properly documented.

6.12 Versions of Forced Coagulation

For Forced coagulation, the ICC generates brief voltage pulses with a high peak voltage. In this way, an effective hemostasis is achieved even with very small-surface electrodes, such as with TUR resection loops or laparoscopic retractors. However, these voltage pulses can cause more or less intensive disturbances in other electronic equipment, such as in video monitors. The Forced coagulation of the ICC can therefore be adapted via Test program 12 in regard to the maximum adjustable peak value of the voltage pulses according to the respective application purpose.Three different versions of Forced coagulation are available for selection:

Version 1 (Standard version)

In this version, the peak value of the voltage pulses increases as a function of the power limitation in the range from 1 watt to 30 watts continuously to 1,300 V_p. Above 30 watts power limitation, the peak value of the voltage pulses is limited to a maximum of approx. 1,300 V_p. This standard version is set and stored on all units in the ICC 350 model series.

Version 2

In this version, the peak value of the voltage pulses continuously increases to 2,300 V_p as a function of the power limitation in the range of 1 watt to 80 watts.

Version 3

In this version, the peak value of the voltage pulses increases continuously to 2,300 V_p as a function of the power limitation in the range of 1 watt to 30 watts. Above 30 watts power limitation, the peak value of the voltage pulses is limited to a maximum of approx. 2,300 V_p.

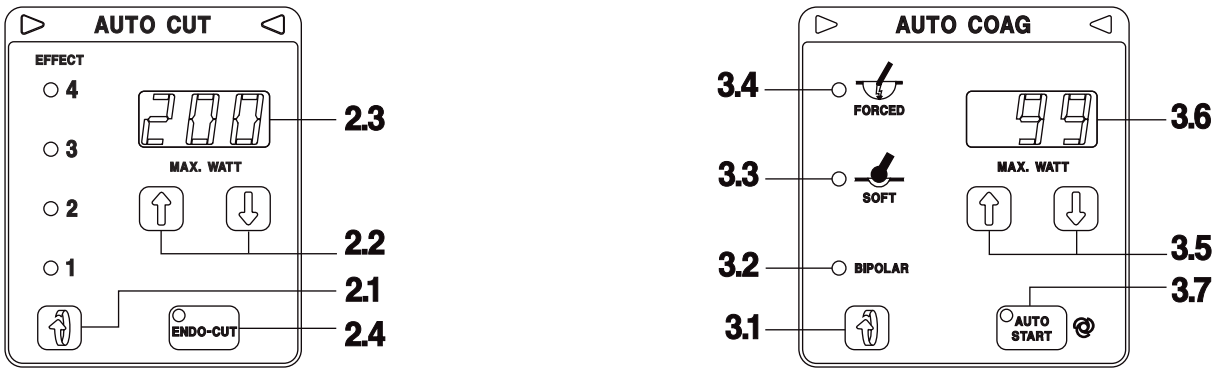
WARNING!

If Version 2 or 3 is stored in memory, the unit briefly displays the current version every time after the power switch is switched on. Standard version 1 is not displayed.

In addition, any change of the version of Forced Coagulation must be properly documented.

6.13 Basic setting and custom programming of the basic setting

If the unit is briefly (approx. 15 s) switched off and on again, the previous setting on the front panel appears and the unit can be used again immediately. If the unit is switched off for longer and switched on again, a freely programmable basic setting for the front panel appears, whereby all displays 2.3, 3.6 blink and the unit cannot be activated until this basic setting is confirmed by pressing any key. Then the displays are continuously illuminated and the unit can be used immediately in this basic setting. If necessary, all settings on the front panel can now be changed. After switching the unit off and on again after a longer period, the basic setting appears again. If this basic setting proves to be inappropriate for the intended use of the unit, it can be individually changed as follows.



1. Switch off the unit.

2. Press key 2.1 and switch on the power switch.

   On display 2.3 appears "Pr" and on display 3.6 appears "1", i.e. Test program 1 for changing the basic setting has been called up.

3. Press key 2.1. This activates Test program 1. The last stored basic setting appears. If however no basic setting has been programmed by the user, "—" appears on displays 2.3, 3.6.

4. Set the required basic setting.

5. By switching off the unit, this front panel setting is automatically stored as the new basic setting and appears automatically after every longer (approx. 15 s) period the unit is switched off and on again.

The unit is equipped with a specific front panel basic setting. The specific basic setting is defined at the factory and cannot be changed by the user. This specific basic setting only appears if the basic setting freely programmable by the user is lost due to an error. For the ICC 200 unit, the following specific basic setting is defined at the factory:

AUTO CUT EFFECT	3
AUTO CUT MAX.WATT	120 watts
ENDO CUT	switched on
T-on time	50 ms
T-off time	750 ms
Monopolar SOFT COAG	60 watts
Monopolar FORCED COAG	60 watts
Monopolar ARGON COAG	60 watts
AUTO COAG BIPOLAR	40 watts, AUTO START switched off

7 CLEANING AND DISINFECTION OF THE UNIT

7.1 Cleaning and disinfection of the unit

The unit housing should only be cleaned and disinfected with nonflammable and nonexplosive agents. Make certain here that no moisture penetrates into the unit.

We recommend a spray or wipe-down disinfection. However, the information from the disinfectant manufacturer absolutely must be observed here.

WARNING!

If cleaning or disinfection of the unit with flammable or explosive agents unavoidable, this must be completely evaporated from the unit before switching on the unit.

Use no alcohol or disinfectant products with an alcohol base. The surface coating on the front plate may become detached.

8 PERFORMANCE CHECKS

Before every application, the user should check the functional efficiency of the unit and the accessories. The ICC is equipped for this with various automatic performance checks that, each time the power switch is switched on, are performed briefly and then signal and display recognized errors. However, not all possible errors are automatically detected and displayed.

8.1 Automatic performance test after switching on the unit

Each time the unit is switched on, it goes through an automatic performance check. If performance errors are detected here, these errors are signaled acoustically and an error number assigned to the respective error is displayed. The following performance errors of the unit and of accessories connected to the unit can be automatically recognized:

1. If a key on the front panel is depressed or shorted out due to an error once the power switch is switched on, this error is signaled acoustically after switching on the power switch and indicated by an error number.

2. If a key on the electrode handle is shorted out or bypassed at low resistance (e.g. due to moisture in the electrode handle) due to an error or depressed while the power switch is switched on, this error is signaled acoustically after the power switch is switched on and indicated by an error number.

3. If the contact of a footswitch is shorted out due to an error or if a pedal is stuck or a pedal is depressed while the power switch is switched on, this error is signaled acoustically and indicated by an error number.

8.2 Automatic performance check during activation

After every activation, the unit goes through an automatic performance check. If performance errors are determined here, these errors are acoustically signaled and an error number assigned to the respective error is displayed. The following performance errors of the unit and of accessories connected to the unit are automatically recognized:

8.2.1 Check of the HF output voltage

If the HF output voltage deviates from the set HF output voltage when activating a certain operating mode, e.g. CUTTING or SOFT COAGULATION, the unit produces acoustic warning signals and displays this error with an error number (see Chapter 8.3 “Error list“).

8.2.2 Automatic check of the neutral electrode

If the connection to the neutral electrode is interrupted during activation, or if the contact resistance (only for a divided neutral electrode) is too high, the unit switches the HF generator off, produces an acoustic warning signal and displays the error with an error number.

8.3 Automatic error documentation

Error numbers (ERROR No.) are assigned to the various errors recognized by the error recognition system. If an error occurs, it is not only immediately reported visually and/or acoustically, but also the corresponding error number is additionally stored in the unit, where it then also remains stored when the unit is switched off. The last respective 10 error numbers can be called up at any time as follows via Test program no. 2.

Calling up the test programs:

- In the AUTO CUT field, press the EFFECT key with the unit switched off and simultaneously switch on the power switch.
- In the AUTO CUT display, Pr = Program appears,
- In the AUTO COAG display, 1 = Test number 1 appears.
- By pressing the ⇑ or ⇓ key in the AUTO COAG field, the required test program number is selected.
- By pressing the EFFECT key in the AUTO CUT field, the required test program is started.
- End the test program by briefly switching off the power switch.

Calling up the stored ERROR numbers

- Call up Test program no. 2 (see above) and start.
- By pressing the ⇑ or ⇓ key in the AUTO COAG field, memory locations 1 to 10 are called up.
- In the AUTO CUT display, the number of the memory location appears.
- In the Auto COAG display, the error number appears.
- The cause of error corresponding to each error number is listed in the error list (see above).
- End this test program by briefly switching off the power switch.

Error No.	Error	How to proceed
0	No error	
1	No HF output voltage	Notify the Technical Service
2	HF output voltage too high	Notify the Technical Service
3	No HF output voltage	Notify the Technical Service
4	HF output voltage too high	Notify the Technical Service
6	Activation error	Notify the Technical Service
7	Activation error	Notify the Technical Service
9	Time limit exceeded	Heed maximum time limit
10	Erroneous setting of the AUTO CUT function field during activation	Before activation of a cutting mode, the AUTO CUT function field must be completely set
11	Erroneous setting of the AUTO COAG function field during activation	Before activation, the AUTO COAG function field must be completely set
12	Erroneous setting of the AUTO BIPOLAR function field during activation	Before activation, the AUTO BIPOLAR function field must be completely set
13	The contact surface between the neutral electrode and the patient is too small or the neutral electrode was not connected to the unit. This error is recognized and reported in the Standby mode or during activation of the unit. **Only for NESSY Version 2** Error in the connection between the neutral electrode and unit **Only for NESSY Version 3** Short between the two contact surfaces of a divided neutral electrode or in the cable to the neutral electrode	Use a sufficiently large neutral electrode and apply the entire surface. Check the connection of the neutral electrode to the unit. Check the connection between the neutral electrode and unit. Probably a faulty cable or faulty plug Eliminate short or exchange cable
19	The contact surface between the neutral electrode and the patient was too small	Use a sufficiently large neutral electrode and apply the entire surface.
20	The neutral electrode was applied in the incorrect direction	See Chapter 4.3.3 NESSY
21	The neutral electrode was applied in the incorrect direction	See Chapter 4.3.3 NESSY
22	When switching on the power switch, the yellow pedal on the footswitch or the yellow key on the electrode handle was already pressed	Check whether there was an operator error or whether the yellow pedal of the footswitch or the yellow key on the electrode handle is defective
23	When switching on the power switch, the blue key on the electrode handle connected to the CUT/COAG socket was pressed	Check whether there was an operator error or whether the blue key on the electrode handle or the cable for the electrode handle is defective
25	When switching on the power switch, the blue pedal was already pressed	Check whether there was an operator error or whether the blue pedal is defective
26	When switching on the power switch, there was an electrically conductive connection between the two poles of the bipolar instrument	Always be certain that bipolar or monopolar active electrodes or instruments are laid onto electrically nonconductive surfaces

27	The internal temperature of the unit was too high. The maximum HF power was automatically reduced.	Always set up the unit in such a way that air can reach the housing.
28 to 29	These errors concern functions in the unit	Please notify the Technical Service
30	The load resistance of the unit was too low	Either the contact surface of the active electrode was too large or the power limitation set too low, or there was contact between an active electrode and a metallic instrument, e.g. trocar sheath.
31	The HF generator of the unit was overloaded too long. The maximum power output was automatically reduced.	The unit can supply briefly more than 200 watts power. More than 400 watts, averaged over 1 second, are not permitted for reasons of safety.
32	The instrument at the monopolar socket is activated by two switches at the same time, e.g. by the fingerswitch and footswitch. Fingerswitch, footswitch defective.	Always activate instruments with one switch only. Please inform Technical Service.
33	The instrument at the monopolar socket is activated by the fingerswitch. During activation, the instrument is activated by the footswitch. The fingerswitch is deactivated. The footswitch remains activated. (Reverse also possible) Fingerswitch, footswitch defective.	Always activate instruments with one switch only. Please inform Technical Service.
34	The instrument at the bipolar socket is activated by two footswitches at the same time. Footswitch defective.	Always activate instruments with one swith only. Please inform Technical Service.
35	The instrument at the bipolar socket is activated (footswitch, Auto Start). During activation, the instrument is activated by the footswitch. The instrument is deactivated. The footswitch remains activated. Auto Start, Auto Stop, footswitch defective	Always activate instruments with one switch only. Please inform Technical Service.
36	The Auto Start key was pressed while the coagulation electrode was already touching the tissue	Always first set the required activation mode and then apply the coagulation electrode to the tissue to be coagulated
37	This error concerns functions in the unit	Please notify the Technical Service
38	Short between the two poles of a bipolar instrument, i.e. a bipolar forceps	Avoid shorts
39	Not available	
40 to 49	This error concerns functions in the unit	Please notify the Technical Service
50 to 51	Errors in a front panel key	Please notify the Technical Service

CAUTION
This error list contains error descriptions relevant only to the operator.
An expanded error list, which particularly describes technical errors, can be found in the technical service documentation.

9 SAFETY CHECKS

To prevent a reduction in safety for the unit due to age, wear etc., § 6 of the regulation concerning the installation, operation and use of active medical products (BetreibVaMP) prescribes regular safety checks. The operator must have the safety checks which have been established for this unit properly performed to the prescribed extent.

The following safety checks have been established for the ICC :

- Inspection of inscriptions and instruction manual
- Visual inspection of the unit and accessories for damage
- Inspection for electrical safety according to EN 60 601-1.
  a) Grounded conductor inspection
  b) Leakage current inspection
- Performance test of all switches and control lamps on the unit
- Inspection of the monitoring devices
- Inspection of the automatic start mode
- Measurement of power output in the CUT operating mode.
- Measurement of power output in the COAGULATE operating mode.
- Measurement of the high-frequency capacities in the various operating modes
- The high-frequency surgical unit must undergo a safety check at least once a year.

The results of these safety checks must be entered in the medical product logbook.

If deficiencies are found during the safety checks, by which patients, employees or third parties could be endangered, the unit must not be operated until these deficiencies have been rectified by a professional technical service.

10 MAINTENANCE, CARE AND DISPOSAL OF THE UNIT

10.1 Maintenance of the unit including reusable accessories

Maintenance of the unit including the reusable accessories includes preventive and corrective measures for servicing. Therefore established, regularly performed safety checks (see Chapter 9) represent preventive measures, while changes and repairs can be summarized under the category of corrective maintenance. Through regular maintenance, the unit including the reusable accessories should be kept within the required status specified in the technical data, and operational readiness and safety are guaranteed for this until the next maintenance date.

10.1.1 Changes and repairs

Changes and repairs must not reduce the safety of the unit and its accessories for the patient, the user and the surroundings. This is considered fulfilled if structural and functional features have not been changed at the expense of safety (DIN 57 751-1/VDE 0751-1). Changes and repairs to the unit, in consideration of the special safety requirements for high-frequency surgical units, must only be performed by the manufacturer or by persons expressly authorized to do this by him. If unauthorized persons perform improper changes or repairs to the unit or accessories, the manufacturer assumes no liability. Additionally in this case, the guarantee claim becomes void.

10.2 Care of the unit

Effective protection of the unit from damage also includes, in addition to proper operation and maintenance, the safe set-up of the unit. This also includes, in addition to safe fixation of the unit to its base, its protection from moisture, contamination and contact with flammable or explosive substances. To ensure good radiation of unit heat resulting from operation, air circulation around the cooling fans and the heat sink must not be impeded.

10.3 Disposal of the unit

The unit can be disposed of at the end of its useful life as standard electronic scrap.

11 CONDITIONS OF GUARANTEE

11.1 Customer service

If you are interested in a service contract, please contact ERBE Elektromedizin or an authorized retailer. Do you have questions regarding high-frequency surgery, the ICC or on this instruction manual? Wish you like the latest scientific publications on high-frequency surgery? Please contact an ERBE employee or your local branch office. We would be glad to help you.

11.2 Conditions of guarantee

The unit and accessories must be immediately examined upon receipt for defects and shipping damage. Claims for damage compensation in this regard are only considered valid if the Seller or Shipping agent is immediately notified. A damage report must be filled out.

The term of guarantee for the ICC is 3 years, for accessory parts 6 months, calculated from the date of delivery. A claim of guarantee can only be made when the properly completed guarantee certificate is presented.

The scope of the guarantee encompasses no-cost repair of the unit, provided the damage was caused by a material or manufacturing error. Other claims, particularly claims of damage compensation, are excluded.

Repair must only be performed by ERBE, one of our representatives, or by an authorized retailer. The claim of guarantee becomes void if improper changes or repairs were made.

Through guarantee performances, the guarantee is neither extended nor renewed.

12 INFORMATION ON ELECTROMAGNETIC COMPATIBILITY (EMC)

Where EMC is concerned, medical electrical equipment is subject to special safety measures and must be installed and commissioned according to the EMC instructions stated herein.

Guidelines for avoiding, recognizing, and rectifying unwanted electromagnetic effects on other equipment or systems that are the result of operating the ICC electrosurgical unit.

When ICC electrosurgical units are activated, disturbance of other equipment or sys-tems in the immediate vicinity can occur. This can be recognized as, for example, image artifacts in imaging devices or unusual fluctuations in measured value dis-plays.

Such disturbances from an activated electrosurgical unit can be reduced by placing it further away and/or carrying out suitable shielding measures on the equipment or system experiencing disturbance.

When the ICC electrosurgical unit is in the non-activated state, interference with other equipment in the immediate vicinity does not occur.

ATTENTION

The use of internal cables other than those specified in the Service Manual may result in increased emissions or decreased immunity of the equipment.

ATTENTION

The equipment should not be used adjacent to or stacked with equipment, other than with that which is intended for this purpose. If adjacent or stacked use is necessary, the entire system should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration - electromagnetic emissions		
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
HF emissions CISPR 11	Group 1	In the stand-by state the equipment uses HF energy only for its internal function. Therefore its HF emissions are very low in the stand-by state and are not likely to cause any interference in nearby electronic equipment.
HF emissions CISPR 11	Class B	The equipment is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with non-conductive synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4- 4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity			
The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile HF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance. The separation distance is calculated from various equations depending on the frequency of the portable and mobile HF communications equipment:
			Recommended separation distance
Conducted HF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms}	Equation 1) $d=1.2\ P^{1/2}$
Radiated HF IEC 61000- 4-3	3 V/m 80 MHz to 800 MHz	3 V/m	Equation 2) $d=1.2\ P^{1/2}$
	3 V/m 800 MHz to 2.5 GHz	3 V/m	Equation 3) $d=2.3\ P^{1/2}$
			P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. d is the recommended separation distance in metres (m). Field strengths from fixed transmitters, as determined by an electromagnetic site surveya) should be less than the compliance level in each frequency rangeb). Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and manufacturer's declaration - electromagnetic immunity

Note 1: At 80 MHz equation 2) applies At 800 MHz equation 3) applies

Note 2: These guidlines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed HF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.Über den Frequenzbereich von 150 kHz bis 80 MHz ist die Feldstärke kleiner als 3 V/m.

Recommended separation distances between portable and mobile HF communications equipment and the equipment

The equipment is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the equipment can help prevent electromagnetic interference. This can be achieved by maintaining the minimum distance recommended below between the communications equipment (transmitters) and the equipment. The minimum distance depends on the maximum output power and the frequency of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d=1.2\ P^{1/2}$	**80 kHz to 800 MHz** $d=1.2\ P^{1/2}$	**800 MHz to 2.5 GHz** $d=2.3\ P^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance can be determined using the equation applicable to the frequency of the transmitter. P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the frequency bands between 80 MHz and 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 2: These guidlines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.